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# Expanded horizons for HIV treatment and prevention

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**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.





**Expanded horizons for HIV treatment and prevention**

This edition of *HIV Australia* explores the changing landscape of HIV treatment and prevention in the light of new understandings about early treatment, treatment as prevention (TasP) and pre-exposure-prophylaxis (PrEP).

The global HIV response has reached a pivotal point, with research confirming the answers to some important questions. We now know that early antiretroviral treatment offers better health outcomes for people with HIV than delayed treatment; PrEP is a highly effective HIV prevention method; and HIV treatment dramatically reduces the risk of onward transmission.

While the big picture science about these issues is largely settled, other questions remain. Health promoters, researchers and policy makers must grapple with the implications of these findings in 'real world' environments; and to ensure success, advocacy and education about these issues must be scaled up.

These new approaches to HIV treatment and prevention present huge opportunities for people living with HIV and the communities that HIV disproportionately affects; however, there are also concerns which need to be addressed. The ramifications of TasP, PrEP and early treatment impact various communities and individuals in different ways, and so cannot be dealt with in broad brushstrokes.

A key question is how do we ensure that new approaches to prevention and treatment are implemented without impinging upon human rights or eclipsing existing HIV prevention strategies?

These multifaceted debates must be teased out to ensure that the expanded options for HIV treatment and prevention are capitalised on to greatest effect – without coercion and without fuelling stigma.

The articles in this edition outline a range of issues and different viewpoints, aiming to enrich ongoing conversations about new approaches to HIV treatment and prevention – and, most importantly, to enhance understanding of implementation issues for the people at the centre of these debates.

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# An early START: major study finds early HIV treatment is best

By **Bill Whittaker**

A major development in the 'when to start' HIV antiretroviral treatment debate was the announcement in May 2015 that a large randomised controlled clinical study called START[1] has been stopped early after the study's independent data and safety monitoring board (DSMB) found compelling evidence that the benefits of starting antiretroviral treatment immediately at CD4+ cell counts above 500 cells/mm$^3$ outweigh the risks[2,3]. The findings support offering HIV treatment to all people with HIV, regardless of CD4+ cell count.

For many working in the HIV field, this is a significant announcement, as the question of when is the best time to start antiretroviral treatment has been the focus of much research and debate since the first antiretroviral drugs became available over 25 years ago.

At face value, it seems obvious that if you have a life-threatening disease and there are treatments available, you would start treating right away. However, that presupposes that the treatments work long-term and that they are tolerable and affordable. For HIV treatment, the reality is that it has taken decades to develop today's modern antiretroviral drugs. It has also taken decades of research to gain essential knowledge about HIV disease and its consequences, which provide the foundations on which effective antiretroviral drugs can be developed.

The START study announcement highlights the long and remarkable story of antiretroviral treatment development – and the debate about when is the best time to start using treatment. This goes back to zidovudine (AZT), the first antiretroviral, which became available in Australia in the late 1980s.

AZT provided a remarkable breakthrough. Finally, several years after the first reports of AIDS[4,5,6], a treatment offered hope. However, enthusiasm about AZT was soon tempered by the reality that it provided only short-term benefit to people with advanced HIV disease. Also, AZT had serious toxicities and drug resistance developed quickly. Added disappointment came later from the findings of the UK-French Concorde[7] clinical trial, which cast doubt on the value of using AZT earlier in people with symptom-free HIV disease.

After AZT's release, antiretroviral drug development evolved slowly over the early 1990s – a time where AIDS-related deaths and illness were at their peak in Australia and many other countries. The relatively few new drugs developed in this period had similar shortcomings to AZT. Based on these limitations, it seemed prudent to reserve antiretroviral treatment for people with more advanced symptomatic disease and/or lower CD4+ cell counts (CD4+ cell counts help measure immune system health), typically using a threshold of around 200 to 500 CD4+ cells to consider starting treatment.

A breakthrough occurred in 1994, when two major clinical trials[8,9] found that combining antiretroviral drugs delivered a better clinical outcome than using drugs one by one (monotherapy). This finding heralded the era of 'combination HIV treatment', which called for antiretroviral drugs to be combined to maximise their impact and help reduce the problem of antiretroviral drug resistance.

As noted earlier, progress in developing better antiretroviral drugs is obviously linked to gaining knowledge about HIV and the course of HIV disease. By the middle of the 1990s, much had been learned about HIV and its prevention and treatment. However, there were also big gaps in knowledge, and this included not having definitive evidence to guide decisions about when to start antiretroviral treatment in early HIV disease.

The approach of deferring antiretroviral treatment was challenged by Dr David Ho of the Aaron Diamond Institute (NYC) in 1995 when he famously wrote that it was time to 'Hit HIV, Early and Hard'[10]. Ho and colleagues proposed that there was no latency in HIV disease and that the HIV virus caused damage from very early HIV infection onwards. Ho went further and predicted that it may actually be possible to eradicate HIV if potent drugs were used early in the course of HIV infection.

Around the same time, a powerful new class of HIV antiretrovirals called 'protease

inhibitors' became available, along with better diagnostic tests (such as viral load testing to measure how much HIV replication is occurring in the body). There was tremendous excitement over these advances, with the International AIDS Conference in Vancouver in 1996 now synonymous with their introduction. As noted by Dr Kevin DeCock of the US Centers for Disease Control and Prevention (CDC), 'Conference delegates were stunned by presentations of individual case histories of patients dying of AIDS who were rescued by ART, colorfully referred to as "the Lazarus effect".'[11]

However, these more effective antiretrovirals, including the first protease inhibitors, still carried with them various limitations, including complex dosing schedules and often debilitating toxicities and side effects. A significant number of people continued to experience antiretroviral treatment failure during this time.

A caution around early use of treatment arose in 2000, when Professor Andrew Carr and colleagues from Australia identified a syndrome in HIV patients involving body shape changes, lipid abnormalities and other toxicities, which were likely linked to protease inhibitor drugs.[12,13] Later, these abnormalities were also linked to some other older antiretroviral drugs and it was also found that HIV itself was a likely contributor to the syndrome.

HIV treatment guidelines of the time reflected the limitations of some protease inhibitors and other antiretrovirals, and they generally supported clinicians and patients using a 200 to 500 CD4+ cell count range as the threshold for starting HIV treatment. Relatively few people commenced treatment at high CD4+ cells above 500.

Notwithstanding the limitations of HIV antiretrovirals, their effect on disease progression, sickness and death has been absolutely dramatic from the mid-1990s onwards. HIV-related mortality and morbidity rates have plummeted in many countries, including Australia. Despite predictions that HIV treatment could never be successfully delivered and sustained in lower income countries, treatment success stories emerged, including in Africa where the burden of HIV is greatest. However, treatment in developing countries was (and still is) often restricted to people with very advanced HIV disease, resulting in many examples where illness and death could have been avoided through earlier treatment access.

Today, we have a very clear picture of what constitutes 'gold standard' HIV antiretroviral treatment – where antiretrovirals need to be potent, easy to take, have minimum side effects and be affordable. Over the past 15 years, a host of new drugs in different drug classes have been successfully developed in line with this 'gold standard'. This focus continues today, with various novel antiretroviral treatments in development, as well as single tablet, once-daily formulations of HIV antiretrovirals, some of which are already available through Australia's Pharmaceutical Benefits Scheme (PBS).

As better antiretroviral drugs have become available, as well as long-term data demonstrating their safety and effectiveness, debate has continued about the optimum time to use them. Some clinicians believe that the 'when to start' treatment question is already answered based on expert opinion and various studies finding health benefits in not delaying treatment. Other eminent clinicians have not agreed, citing for example a lack of evidence for using antiretrovirals in asymptomatic HIV-positive people with higher CD4+ cell counts (e.g. a 500 CD4+ cell count or higher). Community advocates have also had differences of opinion about when to start treatment based on their interpretations of the evidence.

During 2008, enthusiasm grew for a clinical study to answer – once and for all – the question of when to start HIV treatment, and to do this via a large multi-centre randomised clinical study in order to provide the highest level of evidence. It was decided that the study would be conducted by the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)[14] with funding from the US National Institute of Allergy and Infectious Diseases (NIAID). Activists, clinicians and scientists worked on the study design and set up a network of coordinating centres in several countries, including Australia. It should be noted that some clinicians and activists questioned whether such a large investment in a major study to answer this question was warranted, and whether it would be overtaken by other scientific developments and not be completed.

The START ('Strategic Timing of Antiretroviral Treatment')[15] study got underway in early 2009 with the aim of defining the optimal time for people with HIV to begin antiretroviral treatment. The study enrolled healthy, asymptomatic, HIV-positive people whose level of CD4+ cells exceeded 500. The primary objective of the study was to determine whether starting antiretroviral treatment immediately would lead to a lower risk of AIDS, other serious illnesses or death compared to waiting until a person's CD4+ cell count fell to 350 cells. The study was scheduled to end in 2016, subject to regular review by a data and safety monitoring board (DSMB).

Australian involvement in START was led by Professor Sean Emery and colleagues from the Kirby Institute, via a network of clinicians around Australia. Community involvement was a particular feature of START and of the INSIGHT Network, with the National Association of People Living with HIV Australia (NAPWHA) being involved in the study from its beginning in 2009, and NAPWHA's CEO, Jo Watson, serving on the INSIGHT international coordinating group. Over 100 Australians volunteered to be part of START, and along with

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4,500 other participants from around the world, these individuals deserve enormous credit for volunteering for the study and participating in it over several years.

The HIV treatment and prevention field has continued to evolve since START got underway in 2009, with a growing body of scientific evidence and expert opinion favouring starting HIV treatment early, as soon as the patient is ready. Research on the impact of treatment on HIV transmission provided a major advance in prevention, with the HPTN 052 study[16] (released in 2010) demonstrating that antiretroviral treatment reduced HIV transmission from an HIV-positive partner to an HIV-negative one by at least 96% in heterosexual couples. The PARTNER study[17] (presented in 2014) found a similar result among men who have sex with men. The TEMPRANO study[18] (presented in 2015) lent support to the view that the threshold for starting treatment should shift from a CD4+ cell count of 500 to whenever the patient is ready to start.

Reflecting these and other developments, most HIV treatment guidelines today recommend that all people with HIV should be offered antiretroviral treatment, irrespective of their CD4+ cell count, while also noting that the level of evidence for such a recommendation (for people with higher CD4+cell counts) is largely based on non-randomised studies and expert opinion. In Australia, we follow the US Department of Health and Human Services HIV Treatment Guidelines[19] which were the first guidelines to recommend (in 2013) that antiretroviral treatment be offered to all people with HIV who are ready to start treatment, irrespective of their CD4+ cell count.

The question of when is the best time to start antiretroviral treatment was addressed in a 2014 communiqué from the Australian Society for HIV Medicine (ASHM), which proposes the principle that all people with HIV should consider commencing treatment, while noting that the strength of evidence varies.[20] Treatment targets recently set under Australia's National HIV Strategy[21] and endorsed by all Australian Health Ministers call for antiretroviral treatment coverage of 90% among people with HIV, in recognition of the individual and public health benefits of being on antiretroviral treatment.

As stated previously in this article, on May 2015 the START study was stopped[22] over a year early, after the DSMB for the study found compelling evidence that the benefits of starting antiretroviral treatment at CD4+ cell counts above 500 cells outweigh the risks. Specifically, the DSMB found that over an average follow-up of three years, the risk of AIDS, other serious illnesses or death was reduced by 53 percent among those in the early treatment group compared to those in the deferred treatment group.

These are the headline findings of START, but we can expect START to be a study that 'keeps on delivering', including through a number of important sub-studies looking at other aspects of HIV clinical management. It is likely that findings from START and the continued analyses of data from the study will provide many valuable insights into HIV treatment and prevention efforts in the years ahead. Many of us are looking forward to reading the full published START study results, which should become available in coming weeks.

However, there are three key messages from START that should be acted on without delay and disseminated widely:

- If you are at risk of HIV, then get tested and test often.
- If you have HIV and aren't taking HIV treatment, you are recommended to consider starting treatment immediately.
- If you are a doctor caring for people with HIV, you should discuss the implications of the START study with patients as early as possible.

There is no doubt that the results from START are a very important development in the global response to HIV. These study results will influence how HIV is treated and prevented around the world, in both developed and developing countries.

It is critically important that all Australian governments and non-government organisations get the message out now about START's findings and its implications for HIV treatment and prevention. Australia should use our new National HIV Strategy to help mobilise the clinical workforce and affected communities around early uptake of HIV treatment.

While there will likely be some differences of opinion about START and its impact, everyone should agree that it is an immensely valuable study in confirming, via a randomised controlled clinical study, that the approach of treating early which is now being implemented in many countries, including Australia, is the best approach to treating HIV. For many people with HIV and their doctors, the clarity of the START findings will help confirm their choices about starting HIV treatment and empower governments, communities and health professionals to redouble efforts towards the goal of ending HIV and AIDS in every country.

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# Don't leave communities behind: developing a new Global Fund strategy

**Opening Plenary delivered at the Civil Society and Communities Bangkok Partnership Forum, 24–25 June 2015.**

On 24–25 June 2015, consultations were held in Bangkok, Thailand, among partners in global health, including civil society, non-government organisations and public health experts, seeking input into a new strategy for the Global Fund to Fight AIDS, Tuberculosis (TB) and Malaria (The Global Fund). The Partnership Forum brought together more than 120 people to focus on developing the Global Fund's strategy for 2017–2021.

The Global Fund is a partnership between governments, civil society, the private sector and affected communities, and is the largest multilateral funder of health programs in developing countries.

In developing the new strategy, the Global Fund is asking how the partnership can achieve more impact, contribute to the Sustainable Development Goals, and accelerate progress for people affected by HIV, tuberculosis and malaria.

Civil society representatives, Zakaria Bahtout from the International Treatment Preparedness Coalition in the Middle East and North Africa (ITPC-MENA), and Maura Elaripe Mea from Igat Hope, Papua New Guinea delivered the opening plenary at the forum, calling for a new a Global Fund strategy that invests in people and human rights. The complete plenary speech is reproduced below.

**Zack:** Good morning ladies and gentlemen. My Name is Zakaria Bahtout. I am 32 years old. I am from Morocco. I work for the International Treatment Preparedness Coalition-MENA. And I am an activist working for injecting drug users and on intellectual property issues.

**Maura:** Greetings, members of the Partnership Forum. My name is Maura Mea. I am from Papua New Guinea. I am 38 years old. I am a living with HIV and I have also had malaria and TB. I have an HIV-negative child and she is three years old.

Today we are here as equal partners, not beneficiaries. We are the implementers of the current Global Fund strategy. We hope you will learn from our expertise and experience as we work to create the new strategy.

**Zack:** We would like to share some of the priorities for the next Global Fund strategy that community and civil society participants share in the Asia-Pacific and MENA regions. We want a Global Fund that is truly global – one that does not leave key populations and vulnerable communities behind, regardless of the income classification of their country.

In the Arab and Muslim countries of the MENA region, men who have sex with men and people who use drugs are criminalised and persecuted. The Global Fund is the only institution that permits us to get services for these populations and has allowed us to begin critical work to protect their rights.

The Global Fund effectively obliged states in our region to begin to provide HIV services for key populations. But if the Global Fund leaves, governments will not support services and advocacy for key populations. Not ever.

My colleagues in Asia tell me that illegal migrants and ethnic minorities are 'key populations,' highly vulnerable to Malaria. But governments do not recognise them, and they cannot access the identity papers they need to access health services. It is only community organisations like ours that reach these key populations. And they rely on donor support, like the Global Fund.

If the Global Fund leaves these countries, how will these key populations affected by Malaria get the services they need?

**Maura:** We want a Global Fund that increases investments in human rights and gender equality programming

If you are woman living with HIV in Papua New Guinea, my country, you are bound to experience violence from your

> speech continues on page 52

# Biomedical prevention: rhetoric and reality

By **Susan Kippax**

Over the last few years, a number of what are typically termed 'biomedical' HIV prevention technologies have been trialled and many found to be efficacious. These include 'treatment as prevention', pre-exposure prophylaxis (PrEP) and microbicides: all of which are based on antiretroviral therapeutic drugs used in the treatment of HIV. They are termed 'biomedical' prevention to distinguish them from so-called 'behavioural' prevention, such as condom use or reduction in number of partners. Although, as most if not all prevention involves changes in behaviours or social practices, the distinction is not a very useful one.

This article focuses on one of these 'biomedical' preventions – 'treatment as prevention' or TasP – and its efficacy and its effectiveness. The prevention method, TasP, is *efficacious* in as much as antiretroviral therapy (ART) lowers the viral load of people with HIV, thereby reducing the risk of transmission to sexual (or drug injection) partners. Whether TasP is *effective*, as distinct from efficacious, is more complex and depends on a number of factors as described below.

Efficacy and effectiveness are defined as follows:

> Efficacy is defined as the 'improvement in health outcome achieved in **individuals** in a research setting, in expert hands, under **ideal** circumstances … "[1].
>
> Effectiveness on the other hand is defined as: ' … the impact an intervention achieves in the real world, under resource constraints, in **entire populations**, or in specified subgroups of a population. It is the improvement in health outcome … "[2] and includes long term and far-reaching population effects.

Effectiveness is dependent not only on the efficacy of the prevention technology but also on the responses of people. Effectiveness, which is the outcome of sustained adoption of efficacious technologies by populations, is a social, political, and economic matter.[3]

## Efficacy of TasP

There is little doubt of the efficacy of TasP – at least under certain conditions. Following on from the ground-breaking analysis of Vernazza, et al. (2008)[4], Cohen, et al. (2011)[5] in their HPTN 052 study – a randomised controlled trial – demonstrated that for stable cohabiting couples (mostly heterosexual) in serodiscordant relationships, the *efficacy* of TasP was 96%. ART does indeed result in lowered transmission risk for the HIV-negative *individual members of cohabiting discordant couples*. However, it is important to note that people who acquired HIV during the HPTN 052 study from someone other than their *cohabiting regular partner* were excluded from the calculation of efficacy. In total, 38 people seroconverted during the trial: 28 of these acquired HIV from their cohabiting partners (with one in the immediate ART group and 27 in delayed ART group), and 10 became HIV-positive as a result of sexual activity outside of their primary relationship.[6] Therefore, the HPTN 052 trial demonstrated efficacy within the context of stable, monogamous, cohabiting relationships.

## Associated rhetoric

The findings of the HPTN 052 trial taken together with earlier mathematical modelling[7] were hailed by many, including Hilary Clinton at the 2012 International

AIDS Conference in Washington, as heralding 'the end of the epidemic'. In other words, the claim being made by many was (and is) that if a large proportion of people living with HIV were on treatment then HIV acquisition would decline and HIV would eventually disappear. There was an immediate call to roll-out TasP, with *The Lancet* editorial (May 21, 2011) endorsing TasP as a population strategy.[8] Indeed, the editorial in *The Lancet* went so far as to state that funding agencies such as President's Emergency Plan For AIDS Relief and the Global Fund to Fight AIDS, Tuberculosis and Malaria 'need to reassess their prevention portfolios and consider diverting funds from programmes with poor evidence (such as behavioural change communication) to treatment for prevention'[9].

## Effectiveness of TasP

What evidence is there for TasP's impact in the real world in terms of lowering HIV incidence, under resource constraints, in entire populations, or in specified subgroups of a population? In some places and some contexts, the results demonstrate an impact – in other places and contexts not.

Some studies have shown a decline in HIV incidence over time in association with widespread uptake of ART. These include: a study in British Columbia, Canada among people who inject drugs, which demonstrated a decline in HIV acquisition[10]; a study among homosexually active men in San Francisco[11]; and two more recent studies focused on cohabiting couples – one in KwaZulu-Natal[12] in a very large population-based prospective cohort study, and a study in China[13]. However, there has been some caution expressed about interpreting the results of the Canadian and San Franciscan studies as evidence for the success of TasP.

The timing of the 2010 Canadian study is pertinent for interpreting their results: there had recently been a large intervention among people who inject drugs that some believe may account for the decline in HIV-transmission. More importantly, no risk compensation is likely among people who inject drugs. Unlike condoms, which are not necessary for sexual engagement, not only are needles and syringes required to inject, it is in people's interest to use clean needles: fewer abscesses, less bruising, better injecting experience, less risk of hepatitis C transmission, etc. With regard to the 2010 San Francisco study, Garnett, et al. note that the 'positive result' may be due to other factors and that one would 'expect a delay between incident infection and an infectious case being diagnosed and reported'[14].

The two more recent studies, cited above, conducted in China[15] and in Hlabisa, KwaZulu-Natal[16], demonstrated a significant and strong relationship between antiretroviral and reduction in HIV acquisition. However, it is important to note that although Jia et al.'s 2013 study confirms the effectiveness of TasP with reference to serodiscordant couples (their study based on 38,862 serodiscordant couples in China showed a 26% reduction in HIV-transmission under real world conditions), they note that 'protection was only significant in the first year'[17]. They are unsure of the reasons for this and comment that the *long-term* durability of the protectiveness of treatment needs to be confirmed in additional studies.

In Hlabisa, which comprises around 60,000 people who were participants in the open population cohort, about 80% consented to be tested for HIV. Antiretroviral coverage rose from 10% to 30–40% of all HIV-infected individuals over a six-year period.[18] Given this proportion of people on antiretroviral therapy is not high when compared with that in Australia and many countries in Western Europe, why the strong and very positive finding? Barnighausen[19] has suggested that in settings such as rural KwaZulu-Natal where increased access to therapy has transformed the community life with many people living with HIV being able to go back to work and lead normal lives, renewed hope has meant that they take more care now regarding HIV transmission. Indeed, Tanser et al. reported a significant increase in condom use among regular partners in the years between 2005 and 2011, which was independent of the strong relationship between antiretroviral coverage and the lowered risk of HIV acquisition.[20] This study clearly demonstrates evidence for the effectiveness of TasP in this setting as well as the absence of any behavioural disinhibition or risk compensation or alternatively the presence of what might be called 'risk reduction enhancement'.

It is possible, as Wilson[21] has suggested, that ART may have less impact in reducing new HIV infections in countries or among populations where very high levels of ART coverage have been reached, as in Europe and Australia – a sort of ceiling effect.

In contrast to the above, in many communities and regions as the number of people on antiretroviral therapy has increased, there has been no concomitant decline in HIV acquisition, for example, in gay male populations in Australia[22], New Zealand[23], in France[24] and Switzerland[25] and the UK and North America[26,27] In these countries, where there are very high rates of antiretroviral uptake and adherence and where population viral load has been shown to have declined, there has been no decline in HIV acquisition. Indeed in many of these countries, there have been increases in HIV acquisition, and unlike in Hlabisa, a decline in condom use.

So while the modelling of Granich, et al. (2009)[28] indicates that TasP could be effective and could under certain model assumptions radically reduce HIV transmission at the population level, other models – using different assumptions – do not (for example, Wilson, et al., 2008[29]; Mei, et al., 2011[30]; Garnett, et al., 2012[31]; Kretzschmar, et al., 2012[32]). As Garnett, et al. discuss, modelling shows that the extent of a reduction in HIV transmission depends primarily on whether optimistic or pessimistic assumptions are made about the programmatic use

The findings of the HPTN 052 trial taken together with earlier mathematical modelling were hailed by many, including Hilary Clinton at the 2012 International AIDS Conference in Washington, as heralding 'the end of the epidemic'.

of antiretrovirals and state that '[o]nly the most extremely optimistic scenarios predict that treatment alone can halt the HIV pandemic, and even these assume that treatment enables reductions in sexual risk behaviour'[33].

## Reality

Many researchers have commented on these and other studies (for example, Mei, et al.[34], Holtgrave, et al.[35] and Wilson[36]. Wilson sums up saying that the examination of data from TasP 'natural experiments' suggests there are limitations to reductions in population HIV incidence.[37] The limitations include the following: risk compensation; difficulties in linking people living with HIV to treatment and retaining them in clinical care; the increasing pool of potential transmitters produced by successful antiretroviral therapy; and high rates of frequent testing required by those undiagnosed. The interplay between serostatus discordance, risk behaviours and detectability of viral load differs depending on the social and political contexts.

In Sydney, Australia, a study has demonstrated that despite around 70% of HIV-infected men being on antiretroviral treatment and a high proportion of these men having undetectable viral load, the per-contact probability of HIV transmission due to unprotected anal intercourse is similar to estimates reported from income rich world in the pre-antiretroviral treatment era.[38] In Australia, there is evidence from behavioural surveillance that unprotected anal intercourse with casual sexual partners is increasing. Zablotska, et al., 2009[39]; Bavinton, et al., 2013[40] have also shown risk compensation among gay men: with gay men with undetectable viral load (and their partners) more likely to engage in unprotected anal intercourse than those with detectable viral load.

To these considerations of the reach and limits of TasP, we would add that if TasP is to involve anchoring HIV prevention efforts in the clinic there is a real risk that it will function to further privatise HIV, making HIV (whether we are talking about treatment or prevention) a matter for individuals or couples, and not for broad public discussion, debate and action. If the early successful response in Australia taught us anything, it is that a public involvement and a collective response are central to reducing HIV incidence: a solely clinic-based response can function to position people as patients or information recipients rather than engage them in collective attempts to devise and develop apt responses to transmission.

## Conclusions

There are few in biomedicine or indeed in social science who doubt the *efficacy* of TasP. For many in serodiscordant relationships, TasP provides a genuine alternative to condom use – especially for cohabiting couples where there is the opportunity for a frank exchange of information and negotiation of risk. However, it is clear that TasP is not always a successful population strategy: TasP is *effective* at the population level **only** under *certain conditions* and **only** in *certain contexts* – not exactly a 'magic bullet'. Cohen, et al., (2012) acknowledge the differences and note that: 'Implementation of ART as prevention faces substantial challenges, including logistical limitations, potential challenges in risk-taking behaviors, and cost'[41]. However, they seem to think that there is a 'best strategy' for the use of antiretrovirals, which has not yet been developed.[42]

Social scientists argue that there is unlikely to be a 'best strategy' because the reasons for the differences between the studies lie in the social and cultural differences in the populations under study and their differing responses. The effectiveness of any HIV prevention strategy is the ***contingent*** outcome of the collective activity of a diverse range of actors both human and non-human, including the mode of prevention being adopted, scientific practices, clinical services, cultural, political and social environments, and the norms, values, and discourses that animate human behaviour or practice.[43] There is no 'best strategy': any particular prevention strategy is likely to change over time, particularly as there are new developments in the field of HIV and in communities' understandings of and access to treatment and different means of prevention.

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**Professor Susan Kippax is a social researcher of international standing with over twenty years' experience. She has an extensive track record in sexuality and illicit drug use research, and has managed numerous programs in the social aspects of the prevention and care of HIV, hepatitis C, and sexually transmissible infections (STIs). This includes serving as Director of the National Centre in HIV Social Research (NCHSR) from 1994–2008. Through her research, teaching and policy advisory roles, Professor Kippax has played a central role in the framing of Australia's response to these blood borne viruses and infections.**

# Promoting treatment for HIV prevention

By **Sean Slavin**

Treatment as Prevention (TasP) has been discussed for several years in light of increasingly reliable scientific research about the efficacy of TasP, the social and sexual practices of communities and individuals affected by HIV. Optimising TasP is a goal of the current national HIV strategy, which aims to 'work towards achieving the virtual elimination of HIV transmission in Australia by 2020'; and to 'increase the proportion of people living with HIV on treatments with an undetectable viral load'.[1]

Over the past six months, AFAO undertook consultations with its members and other experts to identify the key health promotion challenges relating to TasP and its place within ongoing combination HIV prevention efforts. Sixteen interviews were conducted in total; this article summarises some of the main themes which emerged.

## Background

The goal of antiretroviral treatments (ARVs) is to reduce HIV viral load. The viral load test is a measurement of the level of HIV in the blood, as well as a proxy marker for HIV infectiousness. Thus, ARVs have long been understood as an effective prevention tool in a range of contexts including mother-to-child transmission, occupational exposure to HIV and sexual exposure.

The issue of sexual infectiousness received significant attention in 2008, when the Swiss Federal AIDS Commission published a statement that declared under certain conditions, people with HIV who have an undetectable viral load (UDVL) are not infectious to their sexual partners. The conditions included the absence of sexually transmissible infections (STIs) and UDVL for at least six months prior. The statement specifically referred to 'stable' heterosexual couples, which caused uncertainty about the implications for gay male serodiscordant couples.[2]

While the Swiss statement covered the implications of UDVL for individuals and couples, other discussions around the same time focused on the potential population effects. In Australia, many in the HIV sector expressed concern about the potential risks of substituting UDVL for condom use, with one modelling study predicted a fourfold increase in HIV incidence among gay men if rates of condom use declined under these circumstances.[3]

Some scientists working in settings with low rates of condom use, testing and treatment took a more positive view about the potential benefits to population health of increasing both testing and treatment. The province of British Columbia in Canada adopted a 'test and treat' strategy[4] and a model was developed for high prevalence epidemics in sub-Saharan Africa. Granich and colleagues[5] theorised that with universal testing and immediate treatment following diagnosis it would be possible to eliminate HIV transmission.

While Granich's argument used a hypothetical model, many recognised the potential to both reduce HIV incidence and to scale up clinical and treatment services for people with HIV, who had been chronically underserviced in many contexts. Thus a population health approach to prevention also has benefits for individual people with HIV by reducing the morbidity and mortality associated with undiagnosed and untreated HIV cases. The most notable example of such a program is in San Francisco where great success has been achieved in increasing testing and linkage to care.[6]

At the time, population health discussions relied on a range of evidence that suggested ARV treatment reduced the risk of transmission to varying degrees.[7] What was missing was robust evidence that gave a more precise figure for the degree of individual risk reduction. This arrived in August 2011, with results from the HPTN 052 trial showing that UDVL worked to reduce the incidence of HIV by 96% among heterosexual couples.[8]

Evidence for homosexual couples came in 2014, with the release of interim results from the PARTNER Study. At the study's halfway point, analysis indicated that the risk of HIV transmission in anal sex when the HIV-positive partner had an UDVL was 1%. When asked to clarify what this meant in practice, the researchers responded that their best estimate of the actual risk was zero.[9]

Many people with HIV and their HIV-negative partners are highly engaged with these scientific discussions and want to better understand and use the technology to help manage HIV risk in the context of their lives.[10]

## What does 'Treatment as Prevention' mean in an Australian context?

### A population versus an individual approach

Respondents to AFAO's consultation on TasP largely saw it as being both a population health and an individual approach to HIV prevention; however, they usually emphasised one aspect over the other, depending on their particular concerns or those of their communities.

A representative from an HIV-positive organisation spoke about the potential of TasP to allow people with HIV to more fully enjoy their sex life without worrying about transmitting HIV or needing to use condoms. This respondent said that results of HPTN 052 and the PARTNER study meant that for people with UDVL, condoms were no longer necessarily the preferred or even the best method of HIV prevention.

Two social researchers working with serodiscordant couples suggested that individuals and couples are grappling with the personal implications of population health discussions about TasP in different ways. They said that some research participants are using TasP to support condomless sex, while others see it as something to be used in combination with condoms, providing even greater protection against HIV.

Another social researcher said that while TasP has been promoted as an HIV prevention measure, this has primarily been through 'test and treat' programs to reduce the 'community viral load', but without necessarily engaging in detailed discussion about the implications of treatment for individual sexual practice.

Other respondents were cautious about TasP for individuals and emphasised that consistent condom use remains the cornerstone of HIV prevention in Australia. They emphasised the role of TasP within combination prevention, aiming to increase testing and treatment alongside condom reinforcement messages. This additive approach was then extrapolated to individual circumstances where TasP was seen as additional to condoms.

There was broad agreement that increasing the range of ways to reduce risk was a positive step, but whether individuals decided to use more than one option, or only one, was ultimately up to individuals to decide. This decision is informed by available information and guided by a number of factors including personal disposition, comfort or discomfort with risk, personal sexual preferences regarding condoms and the ways in which couples enact intimacy, care and safety.

### Is TasP an effective standalone safe sex strategy for individuals?

According to a senior clinical and epidemiological researcher, it is possible to recommend TasP as a standalone safe sex strategy for individuals under certain conditions; these include restriction of the approach to individuals in ongoing relationships, where the person with HIV is adherent to medication and has maintained and monitored an UDVL for six months or longer.

The principal reason given for limiting the strategy to couples in regular relationships was that TasP relies on a high level of communication about technical issues such as viral load, trust that the person with HIV is adherent to medication and truthful about their viral load results. Managing this could be difficult in casual sexual encounters.

Notwithstanding this, some respondents wanted to guard against the development of a normative view of what constitutes a 'good' serodiscordant relationship because this could stigmatise those who have casual sex or open relationships.

### Treatment commencement

The question of treatment commencement was discussed by several respondents and there was broad agreement about a set of principles that guide our approach on this issue:

- **The decision to start life-long treatment is significant for most people.** Being well prepared is a crucial determinant of ongoing adherence and success. A senior clinician and medical researcher said that preparedness includes a range of clinical and psycho-social concerns.
- **Compulsion or coercion to commence treatment should not be a feature of TasP.** Informed individual decisions to defer treatment should be respected.
- **Treatment should be universally available and easily accessible to all individuals who are willing and prepared to start.** An ongoing concern exists for people with HIV living in Australia whose access to treatment is limited due to Medicare and the Pharmaceutical Benefits Scheme (PBS) ineligibility.

There was broad agreement that increasing the range of ways to reduce risk was a positive step, but whether individuals decided to use more than one option, or only one, was ultimately up to individuals to decide.

Since conducting the consultations, the START study has shown that treatment is beneficial for people with recent infections and high CD4 counts. This removes uncertainty about the balance of individual risks and benefits when treating people with CD4 cell counts at levels higher than 500 and helps health promoters to further focus on treatment preparedness.

### What does TasP involve for individuals?

TasP requires a high level of adherence to medication—higher than 90% of doses per month. TasP also requires regular monitoring of viral load. Current clinical practice involves testing at three-month intervals and this was regarded as sufficient to support a TasP approach. Less frequent testing among stable patients may need to be reviewed if a TasP arrangement exists.

The meaning of an UDVL was cited as variable, socially and culturally contingent and needing clarification through health promotion (see for example: Gagnon and Guta, 2014[11] and Race, 2001[12]). One social researcher described a conflation among some survey respondents between HIV serostatus and undetectability. Some HIV-negative people believe themselves to be undetectable and some HIV-positive people with UDVLs believe themselves to be HIV-negative.

Meanwhile, some HIV-positive people are inventing new ways to describe their status, especially in online hook-up environments that attempt to frame 'undetectable' as a new HIV status, signalling health and reduced infectiousness.[13]

Viral load blips are not uncommon, particularly as tests have become more sensitive. Very low readings are thought to be clinically insignificant and probably not a risk for transmission when the blip is marginal (i.e. <400 copies/ml).[14]

Another social researcher reported that many of their research participants held folk beliefs about viral load and the factors affecting it. These included a common belief that other infections like colds could lead to an increase in viral load. Interestingly, people relying on TasP for sexual risk reduction may vary their sexual practice around such periods to reduce risk in other ways. This suggests that risk reduction within couple relationships can be understood as a process involving ongoing communication and adjustment that is responsive to changing circumstances.

A number of respondents expressed concern about the possibility of creating division or hierarchy among people with HIV according to viral load. While HIV-positive people with detectable viral loads should not be stigmatised or made to feel inadequate, one of the limitations of TasP for individuals is the need for an UDVL.

Regular STI testing was also regarded as important. The recommended frequency depends on behavioural risk but Australian guidelines suggest at least annually for people with HIV (both heterosexual and homosexual) and quarterly if other risk factors are involved (see the Australian STI Management Guidelines at: http://www.sti.guidelines.org.au).

While the residual risk of HIV transmission in the context of TasP may be small, it is nonetheless important that HIV-negative partners in serodiscordant relationships establish a regular HIV testing routine and are aware of symptoms associated with HIV seroconversion illness.

There was a broadly shared view that individual TasP practices should include discussion and understanding of the approach by both partners in order to ensure informed consent to the approach. This inevitably involves disclosure of HIV status by the HIV-positive partner.

The most compelling reason cited for limiting promotion of TasP as the primary risk reduction approach to regular relationships was that complex discussions including disclosure could more reasonably occur between partners who know or are getting to know each other. Given the persistence of stress about disclosure among people with HIV, there was broad support for health promotion to provide more specific support around this issue.

Several respondents raised concerns about the potential legal implications of individuals using TasP as an alternative to condoms, in some jurisdictions. There was, however, endorsement of the harm reduction principle that HIV health promotion should offer advice to empower individuals to reduce the risk of HIV, even when it involves illegal behaviour. There was also acknowledgement that health promotion must address the reality that many couples do not like using condoms and awareness about TasP as an alternative is steadily increasing, in any case.

A number of respondents discussed the positive potential that might arise from a relational and shared approach to treatment and prevention within couples. Mostly, management of HIV takes place outside the context of relationships, in the clinic and the involvement of HIV-negative partners in these practices is generally limited to understanding their partner is well and perhaps being kept informed of viral load results. Given that TasP is a prevention tool that both partners may rely upon, it is worth considering the health information needs of HIV-negative people, including about HIV-related health and treatments. This has the potential to lighten the burden for the person with HIV and engender confidence in the HIV-negative partner.

## Conclusion

The prevention benefits of treatment continue to be a crucial feature of combination prevention in pursuit of national goals to significantly reduce HIV incidence. Treatment as prevention also has potential to reduce HIV-related stigma by reconfiguring what it means to have HIV. Some people with HIV are already claiming 'undetectable' as a new HIV status that encompasses health and reduced infectiousness.

There is growing interest among people with HIV and their sexual partners about the potential of TasP as an individual safe sex strategy that may or may not also include condoms. This represents an opportunity for HIV health promotion to develop clear and consistent advice on how to do this safely. This requires improved HIV health literacy among HIV-negative partners of people with HIV, including more detailed information on treatments, viral load and condom and non-condom based sexual risk reduction. Providing guidance to people with HIV and their partners about sexual risk reduction without condoms may continue to cause concern, including for legal, political and epidemiological reasons. But providing such guidance draws on strong scientific evidence about the safety of the practice and has potential to assist

those individuals and couples wanting better sexual intimacy, less self-stigma and reduced anxiety about transmitting HIV to their partners.

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# PrEP is a key HIV prevention strategy, but how do we chart its success?

By **Clovis Palmer**

## What is PrEP?

Despite tremendous efforts to address HIV worldwide, the rate of new infections remains unacceptably high, demonstrating an urgent need for new prevention strategies. HIV pre-exposure prophylaxis (PrEP) is a new approach that involves the use of antiretroviral drugs by HIV-negative individuals to reduce the risk of acquiring HIV. The daily use of a combination of drugs: tenofovir/emtricitabine (Truvada) as oral PrEP has been shown to be effective in several clinical trials. The convincing data from these studies have prompted the Centers for Disease Control and Prevention in the USA, and the World Health Organization (WHO), to develop and release guidelines recommending the use of oral PrEP for high-risk populations.[1,2]

While the scale-up of PrEP is well under way in many cities in the USA, several implementation questions remain unanswered regarding how PrEP will reach high risk populations within that country and around the globe. Concerns have been raised regarding cost effectiveness, ethical issues, and the possible explosion of other sexually transmissible infections (STIs). Some critics have also pointed to the risk of emergence of resistant HIV strains and adverse side effects.[3,4]

Some argue that PrEP complicates and distracts from the efforts required to design and find an effective HIV vaccine.[5] Others question the public health impact of PrEP scale-up in the real world due to slow uptake, risk compensation[6], poor personal adherence[7,8,9] and, in the context of Australia, the cost effectiveness beyond HIV-negative men who have sex with men (MSM) in a discordant relationship[10].

Internationally, these issues have been the subject of at times acrimonious debates. While the research unequivocally shows that PrEP works in a clinical setting, there are those who sharply oppose it, or cannot see past limitations that could be used as a roadmap to improve its implementation in the real world.

## The supporters and the critics

Personally, I don't think PrEP should be debated in the context of 'for or against'. I find it difficult to comprehend why someone would deny any individual the choice of accessing an HIV prevention method that's been proven to be safe and effective.

Official recommendations support offering PrEP to people at greatest risk of HIV acquisition, but maximising the public health impact of PrEP may require a broader approach – with guidelines akin to those already recommended for people living with HIV.

## PrEP Guidelines

According to current US Food and Drug Administration (FDA) guidelines, PrEP protocol should include:

1) baseline HIV test
2) adherence to daily use
3) periodic (every three months) HIV/STI check-up
4) monitoring of kidney and liver functions
5) use of condoms.

These PrEP support guidelines generally fall into community-based, monitoring, technology, and integrated sexual health promotion approaches. Formalising these approaches beyond PrEP trials toward a more comprehensive roll-out

protocol, in often socio-economically-deprived environments (some where the local language differs from the national language), will be no easy feat.

## Interpreting the efficacy of PrEP

Several randomised clinical trials demonstrated that daily use of tenofovir alone, or in combination with emtricitabine, can reduce the risk of HIV transmission in heterosexual serodiscordant couples, men who have sex with men, transgender women who have sex with men, and sexually active heterosexuals.[11,12,13,14] In these trials, the overall reduction in HIV risk provided by oral PrEP ranged from 0%–75%. The iPrEX study, the first of these studies, provided results that demonstrated an overall risk reduction of 44% in 2,499 enrolled MSM and transgender women from Latin and North America, Asia and Africa.[15]

iPrEX provided the first proof of principle that antiretroviral therapy (ART) is an effective HIV prevention tool. The study also underscored the significance of adherence, providing a 92% risk reduction in those who adhered more consistently to daily pill-taking.[16] Despite the wide range in efficacy estimates in the different trials, the general consensus is that adherence is the single most important factor determining the success of PrEP.

Indeed, studies such as FEM-PrEP[17] and VOICE[18], which were among women only, showed that those who had suboptimal amount of drugs in their blood were not protected from HIV – reinforcing the significance of adherence. This begs the question: how do we calculate an intervention's success? Shouldn't the effectiveness of an intervention also be judged based on its availability and its ease of adherence? Interpretation of the data becomes even more complex when one takes into account the use of condoms by participants in these studies.

Initial concerns that PrEP may not work for women were addressed by other studies; TDF2[19] and Partners PrEP[20] demonstrated a 78–86% effectiveness. However, it does appear that factors other than adherence, such as differential drug penetration in the female genital tract, may partially contribute to a less forgiving nature of PrEP in women who miss doses – the drug being at higher levels in the rectum than in the female genital tract.

Evidence of safety and reduced HIV risk at the individual level has positioned PrEP as an important component of a comprehensive approach to HIV prevention. However, modelling studies suggest that the public health impact of PrEP could be limited by slow uptake, poor adherence, and increases in risk behaviour (risk compensation).[21] In Australia, the only country remotely on track to attain the ambitious UNAIDS target of '90-90-90' by 2020 (90% of all people living with HIV will know their HIV status, 90% of all people with diagnosed HIV infection will be on sustained ART, 90% of all people on ART will have below detectable viral load), PrEP could potentially end HIV transmission in high risk populations. But when we consider this in the wider context of the Asia and the Pacific, the challenges are magnified, and our goal becomes elusive.

## How to overcome the limitations of PrEP?

### Potential side effects

Oral PrEP appears to be generally safe and well tolerated, but has been associated with small yet statistically significant decreases in liver and kidney function and bone mineral density (BMD). These side effects tend to resolve after discontinuation of PrEP. However, the long-term clinical significance of these changes remains unclear, and effects on users with underlying health conditions, and elevated risks of bone, liver and kidney diseases, are unknown. What is evident is the importance of baseline assessment and ongoing monitoring of HIV status, BMD, renal and liver function, and pregnancy.

Promisingly, one clinical trial is trying to shed light on the potential utility of vitamin D supplementation for individuals who use PrEP (CCTG595VitD).[22] This is a good example of where early observations can be used as a roadmap to improve intervention.

### Development of resistant strains

Development of drug resistance is a concern for individuals who use PrEP after unknowingly acquiring HIV, because PrEP may not fully suppress the virus. Fortunately, drug resistance has been rare among PrEP users who were HIV-negative at enrolment.[23,24,25] One approach to allay the fears of HIV drug resistance is to increase accessibility to testing technologies with shorter window periods, such as nucleic acid amplification tests and antigen/antibody combination tests, to discount acute HIV infection prior to PrEP initiation. Another approach is to develop creative strategies to improve adherence.

### Ethical issues regarding availability

The global public health impact of PrEP is not only dependent on how many people use it, but also on who uses it. Thus, prioritising PrEP uptake among those at highest risk is important to maximise its overall impact and cost-effectiveness. At the pinnacle of the risk spectrum are economically marginalised groups in resource-rich and resource-constrained countries, for whom PrEP is not a current option due to economic and structural barriers.

Many critics have cited the demographic of the participants in the iPrEX study: 55%, 15% and 12% from Peru, Brazil and Ecuador, respectively. They question the ethical undertones pertaining to the lack of availability of PrEP for those volunteers or other at-risk populations in these countries. However, it would seem unethical to deny someone the benefits of PrEP. If a woman has a family history of breast cancer, should she be denied the BRAC1/2 genetic test simply because it is unavailable to someone else?

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### Cost-effectiveness

Treatment as prevention, in which an HIV-infected partner with undetectable viral load is in a serodiscordant relationship, is already associated with a 96% reduction in transmission risk[26], which raises the question whether PrEP has limited incremental value in these scenarios. In a recent economic evaluation of the cost-effectiveness of 'on demand' HIV PrEP for men who have sex with men in Canada, considering direct antiretroviral and psychosocial costs along with outpatient, inpatient and emergency department costs, the cost effectiveness ranged from cost-saving to largely cost-effective.[27] But can we truly put a monetary value on averting the experience of stigma that people living with HIV are routinely exposed to? Not to mention the non-negotiable lifelong burden of adhering to daily HIV medication and the impact of laws in many countries that force people with HIV to disclose?

### Barriers

Among individuals who have an interest in PrEP, the lack of access to a health care provider who is knowledgeable or comfortable in talking about PrEP may present a significant obstacle. The high cost of PrEP is indisputably a major barrier to uptake globally, particularly in resource-rich countries where only branded Truvada is currently available. In the US, PrEP can be accessed by private health insurance, and Gilead has implemented a financial assistance program for those without insurance. The extent of financial coverage in other countries is unresearched.

Emphasis should also be placed on increasing physician comfort and confidence in prescribing PrEP. An increased capacity to deliver PrEP could involve galvanising other health care providers such as nurses and pharmacists in prescribing and monitoring PrEP.

Education regarding HIV infection risk and safety concerns will continue to form the fundamental basis of PrEP, highlighted by the iPrEX OLE[28] and US Demonstration Project[29] where low perceived risk of HIV infection, safety concerns, and pill burden, emerged as potential barriers for PrEP use. Negative and judgemental reaction towards PrEP users, referring to them as 'Truvada Whores', has characterised negative media portrayal of PrEP in the US; however, PrEP advocates and users have reclaimed this phrase, proudly wearing 'Truvada Whore' t-shirts in response.

## The future of PrEP: what might it look like?

Naturally, one of the main limitations of PrEP is the same that exists for millions of people living with HIV: pill fatigue. Studies such as the Ipergay trial, evaluating on-demand PrEP with Truvada, have demonstrated an efficacy rate of 96% with four doses per week, suggesting intermittent strategies may be a viable option to pacify the fears of pill fatigue and affordability.[30]

We are likely to see the addition of more convenient formulations including the promising long-acting injectable drugs currently in clinical trials – such as rilpivirine LA (administered monthly), and cabotegravir (administered quarterly), slow-release dapivirine intravaginal rings, gels and more ambitious developments such as subdermal implants and patches, which may limit systemic drug exposure and potential toxicities. It is not too preposterous to imagine a chewable PrEP – perhaps combined with vitamin D/calcium to improve convenience in situations where potable water might be out of arm's reach.

Participants in some studies have expressed interest in incorporating drug-level testing, with results guiding adherence counselling. Integrating technology with many of these strategies has the potential to bring down costs, decrease side effects, reduce pill fatigue and facilitate adherence. Maximising the public health impact of PrEP will require roll-out to be combined with innovative interventions to promote uptake, support adherence and prevent increases in risk behaviour.

PrEP will also be seen for having benefits that go far beyond its direct effect on HIV risk. It will provide an opportunity to engage high-risk individuals with health services that they otherwise may not access. This includes services that are an integral part of the normal PrEP package, such as regular HIV/STI testing, medical check-ups and risk-reduction services.

## What is happening in PrEP research?

Several studies underway are giving us a forecast into the future, including evaluating text message-based adherence interventions, and diversification of demographics to include female and transgender sex workers (PrEP-India, NCT02148094[31]), young heterosexual men and women (CHAMPS, South Africa NCT02213328[32]), young MSM of colour (CRUSH, USA NCT02183909[33]), and MSM and heterosexual men and women (VicPrEP[34] and PrELUDE, NCT02206555, Australia[35]). We should take advantage of technological advancement and social media and text messaging to increase awareness about PrEP.

## Leaving no-one behind

By contextualising research findings and novel technologies to bridge the gap between science and the community, we can endeavour to implement PrEP on a global scale in regions where culture and infrastructure create an environment for practical PrEP roll-out. The work ahead is challenging if optimal access

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to PrEP is to be achieved in resource-constrained countries in Eastern Europe, Asia, Central and Latin America, and the Caribbean, where PrEP trials are absent or minimal. Vital to this will be the plasticity of local governments, where policies will need to be instigated to support successful implementation of this promising HIV prevention strategy. This will ensure that no-one is left behind.

## How can I access PrEP if I am interested?

Truvada is not yet been approved for use as PrEP in Australia; however, most STI clinics have healthcare professionals who are experienced in caring for people with HIV and should be receptive to enquiries about PrEP. Familiarising yourself with credible PrEP-related information and consulting a healthcare provider to discuss your options is important, so that you can make informed choices.

Links to resources and information about current options for accessing PrEP in Australia are available from the Australian Federation of AIDS Organisations (AFAO) website at: https://www.afao.org.au/about-hiv/hiv-prevention/pre-exposure-prophylaxis-prep

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# PrEP: a GP's perspective

By **Fiona Bisshop**

PrEP is the latest big thing in HIV prevention. Pre-exposure prophylaxis is the full term, and it represents an effective strategy for protecting yourself against HIV infection. I would like to give you my perspective on PrEP as a GP who manages HIV infection and sexual health, and sees a lot of sexually active men who are at risk of acquiring HIV.

The reason PrEP has become such a hot topic is that some large-scale international trials have been published which show it is highly effective in preventing HIV transmission. PrEP is also quite simple to take (it's a daily pill) and has relatively few side effects, so it's hardly any wonder guys are starting to come in and ask if they can go onto it.

PrEP should not be confused with PEP (post-exposure prophylaxis) – a 28-day course of antiretroviral tablets which must be started within 72 hours of possible exposure to HIV. Unlike PEP, PrEP is taken before HIV exposure. The most commonly studied and recommended PrEP is a pill called Truvada, which is a combination of tenofovir and emtricitabine. Other drugs are being studied too, but there is no good data on these yet so they are not being recommended at this stage.

## Why PrEP?

So why is PrEP necessary? Unfortunately HIV transmission rates are continuing to rise despite public campaigns to raise awareness around safe sex and regular testing. Condoms don't work for everyone for a variety of reasons – guys who have erection problems find them difficult to use, some guys find them to be a real turn-off and actually hate them, and they're not always around when you need them. The correct use of condoms requires a degree of preparation that doesn't always fit with everyone's lifestyle.

There are many guys out there already using 'informal' PrEP – perhaps taking left over PEP tablets, or using their partner's or a friend's meds, or they may have bought it online or overseas. The benefit of doing this with medical supervision and advice from a doctor is that they will know how to use it effectively, and will monitor for side effects and possible serious reactions, and ensure regular testing for other sexually transmitted infections (STIs).

## Prophylaxis – it's not a new concept

I have heard people use the term 'Truvada Whore', and talk about PrEP in a really negative way, as though it confirms a judgment about a person's character if they are taking it. This is really a symptom of society's attitudes to sex in general. In the 1960s, there was a similar attitude towards women taking the contraceptive pill. It was a new concept and implied a degree of sexual freedom previously unattainable. Really PrEP is not much different, it's about empowering an individual to take control of their own health in a way that fits with their lifestyle.

## PrEP myths

There have been concerns that PrEP is not effective. The evidence would say otherwise. There are now several large trials and demonstration projects from different countries which show that PrEP is very protective against HIV

transmission when it is taken properly. The iPrEX and PROUD studies looked at daily PrEP use, and Ipergay looked at intermittent PrEP. Overwhelmingly, the results of these trials showed that those people who were actually taking the pills properly were protected.[1,2,3]

People have been concerned about the potential side effects and risks to health from the medications, but the studies helped to dispel this myth as well. Some people complained of nausea, headache and weight loss in the first few weeks of taking the pills, but these effects seemed to settle after the first month of use. I like to explain it this way – the drugs contained in the PrEP pill have been used for many years to treat HIV, and so their side effect profile is quite well described and there are unlikely to be any surprises. We know that a small proportion of people who are on these drugs long-term may have some drop in their kidney function, but that this generally returns to normal after stopping the drug. Also most people have a small drop in bone density on the pill, but this does not worsen with long-term use.

You may have heard that PrEP is not available unless you are lucky enough to get into one of the demonstration projects that are running in different cities. This is not true, as PrEP can be purchased either from local or overseas pharmacies with a doctor's prescription. Unfortunately it is not yet listed with the TGA (therapeutic goods administration) or the PBS (pharmaceutical benefits scheme) so a local pharmacy has to charge a high price of over $700 a month. Overseas pharmacies can supply a generic version of high quality for a much lower price of around $130 a month, or $330 when bought in three-month quantities.[4] You will need to email them a copy of your prescription. It may take about two to three weeks for your medication to be delivered after you have put in your online order. Of course if you did manage to get into a local PrEP study then you will be given the drug for free.

An objection raised by some people is that if you get HIV while taking PrEP you will develop resistance to the drugs. I must admit I was worried about this too, but the studies have shown it really isn't a big issue. In fact, the only cases of resistance were in people who didn't realise they were already seroconverting when they started PrEP, and they didn't actually develop serious resistance mutations anyway.[5] So the key to avoiding resistance is to make sure you are most definitely HIV-negative before starting PrEP.

Concerns have also been raised that taking PrEP would lead to more condomless sex and more STIs. In fact the studies have shown this is not the case, and that there was little change in the rates of condom use or STIs in those people taking PrEP.[6]

## Starting PrEP

Before starting PrEP, I talk to patients about its effectiveness and what the possible side effects are. I also mention the possible kidney and bone effects, and how best to monitor for these. I order a baseline blood test to check kidney function, and also to make sure you are HIV-negative. I check you are immune to hepatitis B, and start your vaccination course if necessary. I ask about any other medications you are taking, including over the counter remedies and supplements, in case of interactions. I also usually ask about other drug use, because if you are taking something like crystal meth regularly then you might need more help with sticking to your daily pill.

The most important thing to understand about PrEP before you start it is that it only works if you take it. A bottle of PrEP in the medicine cabinet is no good unless you're opening it every day and swallowing a pill! So I give advice about tricks to help you remember to take it, like pillboxes and phone reminders.

Making sure you're HIV-negative before you start is so important. If there is any concern that you may still be in the window period for testing, I will probably recommend that we delay starting until we're sure you haven't seroconverted.

Symptoms of seroconversion can include sore throat, fever, rash, sore glands, headache and sore joints and muscles. If you were to start PrEP while seroconverting, you would be at risk of developing resistance to the medication, which makes life a little complicated! For this reason I never rely on the results of a rapid HIV test if seroconversion is suspected prior to starting PrEP, as the rapid tests are not quite as sensitive at that very early stage of infection.

When you first start PrEP the recommendation is that you start it five days before you have condomless sex. This just gives the drug time to get into the rectal tissue so it's already in place ready to protect you.

## Monitoring

I recommend a regular three-monthly STI check-up for all sexually active gay men and other men who have sex with men, checking for syphilis, gonorrhoea, chlamydia, hep C, as well as HIV. If you're on PrEP, then I just add a test of kidney function in your regular blood and urine tests. So monitoring PrEP is not that different to a regular STI screening.

## Intermittent PrEP

The best data we have comes from people who took PrEP every day. The other way to take it is intermittently, that is, just from time-to-time when you anticipate you might need protection.

The Ipergay study looked at intermittent PrEP use, where people took their pills a few hours before sex and for two days afterwards. It did provide protection, but the guys in the study were quite sexually active and were taking their PrEP on average weekly, which meant that their levels probably didn't drop to zero in between episodes, so it's hard to know if

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it would still be as effective if you were taking it say monthly rather than weekly. At this stage, there is no recommendation for intermittent PrEP use, and it is something best discussed with your doctor who can look at your individual risk.

## How to stop PrEP

If you've been taking daily PrEP, the recommendation is that you continue it for 28 days after the last exposure.

## Who should take PrEP?

PrEP is suitable for any person who is likely to be exposed to HIV in the future. I would recommend it for guys who have casual partners and frequent condomless sex, guys who attend sex parties, guys who take drugs like crystal which affect their ability to make rational decisions around protection, guys who can't use condoms, guys who are regularly getting rectal chlamydia or gonorrhoea, and anyone who has had to ask for a course of PEP. It's also recommended for those people with a positive partner who is not on treatment, and for heterosexual couples trying for pregnancy, where one partner is positive.

## Who shouldn't take PrEP?

Really there aren't many people who can't take PrEP. It's not suitable if you have kidney disease. It shouldn't be taken by anyone who hasn't had an HIV test and doesn't know their status already.

## PrEP, condoms or both?

I am a strong advocate for the use of condoms, as they protect against a variety of other STIs, but I'm also a realist, and I know that there are many people who are not going to use them in all situations. Ultimately I believe that every individual who believes they might be at risk of HIV should be able to have the choice of going onto PrEP.

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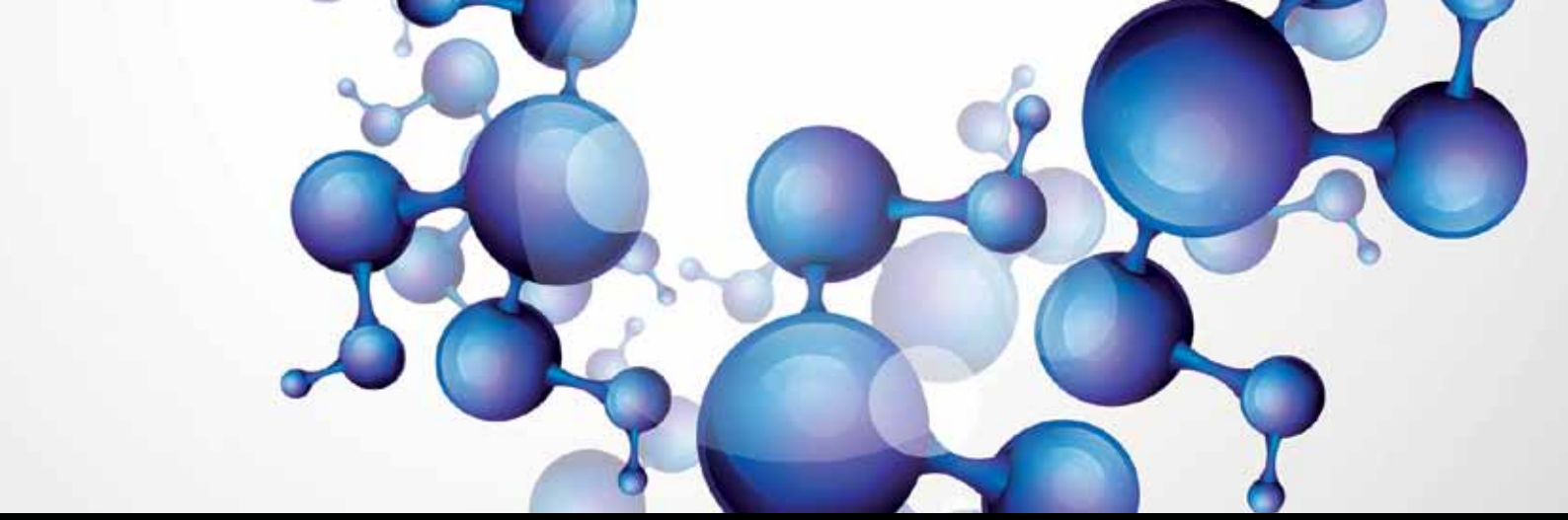

# PrEP works, so how come we are still doing research on it?

By **Bridget Haire**

Pre-exposure prophylaxis (PrEP) – the use of antiretroviral drugs[1] in HIV-negative people – has now been clearly established as an effective HIV prevention method. HIV risk reduction has been demonstrated in five randomised control trials in different populations at high risk of HIV acquisition[2,3,4,5,6] and three effectiveness studies[7,8,9]. In 2012, PrEP was approved by the United States Food and Drug Administration.[10] In 2014, the World Health Organization's Consolidated Guidelines recommended PrEP as an additional HIV prevention choice for men who have sex with men, and for other HIV-negative people in serodiscordant sexual partnerships in all epidemic settings.[11] It is fairly extraordinary then that in 2015, people living in Australia can only access PrEP through small-ish implementation studies in NSW, Victoria and Queensland[12,13,14], through 'off label' prescription (approximate cost $AUD10,000–$13,500 per year[15,16]) or personal importation of generic drug (with a valid prescription).

Access to PrEP was prioritised in 2012 in the Melbourne Declaration[17], an advocacy action statement released by Australia's HIV sector (community, clinicians and researchers) working collaboratively to respond to targets set in the 2011 United Nations Political Declaration on HIV/AIDS[18]. Unfortunately, this advocacy did not translate into policy at government level, and PrEP has been overlooked in key strategic documents. In the otherwise very forward-looking NSW HIV Strategy 2012–15, PrEP access is discussed[19], but no targets or implementation plans are set and it is couched as a Commonwealth issue. In the Seventh National HIV Strategy (dated 2014), PrEP is mentioned in two non-committal sentences that state, 'its place in the prevention response needs to be determined', and it is not listed as a priority action.[20]

## Current access in Australia through demonstration sites

- NSW (PrELUDE): 300 people[21]
- Victoria (VicPrEP): 100 people[22]
- Queensland (QPrEP): 50–150 people[23].

## Moves towards improved access

Gilead, the company that makes the PrEP drugs trenofovir and emtricitabine (Truvada), has applied to have the drug approved for prevention by the Therapeutic Goods Administration. However, getting funded access to the drugs also requires a submission to the Pharmaceutical Benefits Advisory Committee, in order to have the drugs listed on the Pharmaceutical Benefits Scheme. Gilead has not made this submission, and while Gilead did not respond to a request for comment made for this article, AFAO understands that the company does not intend to make such a submission in the immediate future. This will further attenuate time lines for access.[24] Whilst community sector HIV organisations, including AFAO, are committed to trying to improve PrEP access through state-based mechanisms, the pathways to achieve this are unchartered and as yet unclear.

## What do implementation studies measure?

The reasoning behind running implementation studies rather than simply seeking regulatory approval for PrEP is that the population health benefits of PrEP have been perceived by cautious policy makers to be somewhat unclear, firstly because PrEP efficacy has varied in trial sites to considerable fluctuations in adherence, and secondly because of fears of 'risk compensation' – concern that the preventative benefits of PrEP could be cancelled out by increases in risk behaviour.

Data from clinical trials show that PrEP reduces HIV transmission when used correctly[25–32], and that PrEP efficacy is highly dependent on user adherence. The highest rates of adherence, and consequently the highest efficacy to date, has been observed in two recent studies in gay and other homosexually active men in the UK[33] and France[34], which is promising for the Australian context given that there are cultural similarities across gay communities in wealthy industrialised countries.

Implementation studies are a means of getting context-specific information that can be used to cost-benefit analyses. The current cost of PrEP is estimated at about $US 1000 per month, or about $US100 per month for generic PrEP manufactured in India, though such costs vary according to the purchasing power of particular health systems.[35] To estimate the total cost of the intervention, however, costs of regular testing and costs of doctor's

visits for prescriptions would need to be added. Whether the intervention is then cost-effective in terms of HIV infections averted, depends both on the overall level of PrEP efficacy in a population and the background HIV incidence.[36]

Context matters with PrEP, firstly because poor adherence to the regimen could seriously undermine effectiveness; and secondly, because it needs to be introduced in such a way that minimises any perceived conflict between promoting the use of condoms for prevention, versus a biomedical strategy to reduce the risk of infection.

## New qualitative study

The Kirby Institute is commencing a new qualitative study examining how PrEP is currently perceived and used (or not used) by sexually active gay men. The study, What Does PrEP Mean for Safe Sex in Sydney?, seeks to interview sexually active men regardless of serostatus, including men who are accessing PrEP through either the PrELUDE trial or though off-label prescription or personal importation. The study will investigate issues relating to adherence, including the scheduled clinic visits and the HIV and sexual health testing that accompanies PrEP use. Clinicians who prescribe PrEP or who are involved in the PrELUDE study will also be invited to participate in this research, as will community sector opinion leaders who have extensive contact with people trying to negotiate PrEP access.

The study will also explore whether participants consider that PrEP changes the way they negotiate sex or engage in sexual practices, and their perceptions of how this impacts on the normative values concerning HIV prevention ('safe sex culture'). These data will be critical to developing effective health promotion in the combination HIV prevention era – and we hope may also be instrumental in working for broader community access to this prevention intervention for people at high risk of HIV acquisition.

**People interested in participating in the What Does PrEP Mean for Safe Sex in Sydney? study should contact Bridget Haire by emailing bhaire@kirby.unsw.edu.au or phoning 02 9385 1227.**

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# Off-label: the changing boundaries of prevention

By **Dean Murphy**

A recent story on ABC TV's *7.30* called 'PrEP: The blue pill being used to prevent HIV', was an interesting foray by mainstream media exploring the issue of HIV pre-exposure prophylaxis (PrEP). The story follows earlier coverage by SBS Television and ABC Radio over the last year. In recent weeks, I've also been contacted by several community and student media journalists with inquiries about PrEP. This flurry of media activity on the topic suggests that interest in PrEP in Australia is currently very high.

The story on *7.30* featured a range of PrEP users, including one man who is currently taking part in a PrEP demonstration project in Australia, an African-American man accessing PrEP in a relatively straightforward way in the US, one man who sees himself as a potential user of PrEP in the future, and one man who is importing a generic version of Truvada into Australia for use as PrEP. The story also described how 'many gay men are forced to come up with creative ways of obtaining the drug', referring to importation from overseas. Chris, one man in the story, outlined the steps he follows as part of this process.

Importing drugs for personal use (limited to a supply of three months at a time) is perfectly legitimate, and general information about how to do it is provided on the website of the TGA (Therapeutic Goods Administration)[1]. Importantly, importation of drugs needs to be accompanied by a prescription from an Australian doctor. Recently, HIV prevention community organisations such as ACON and Victorian AIDS Council (VAC) began providing advice on personal importation of generic versions of Truvada. The Australasian Society for HIV Medicine (ASHM) also now provides advice to clinicians on managing patients importing antiretrovirals (ARVs) for PrEP, including guidance on importation.

The title of the story was presumably an attempt to make a connection between PrEP, or specifically Truvada, and Viagra (sildenafil) commonly known as 'the little blue pill'. Some media and other commentators in the US have taken this analogy further by dubbing Truvada as a 'party drug', noting also that there is a street market in cocktails of crystal methamphetamine, Truvada and Viagra together – labelled 'MTV'[2]. This underlines how the media as well as research literature often frames gay men's interest in antiretrovirals for prevention in a similar way to illicit drug use, in that ARVs are enacted as unprotected sex. However, despite these similarities in framing, there has not been any serious attempt to think about these different types of drugs together.

## What is PrEP?

An important question is what PrEP *is*, or rather what are the many PrEPs that emerge in different locations? This question is likely to be further complicated by different ways of accessing ARVs for prevention. Although the terms PrEP and Truvada are used almost interchangeably, I would argue that the former is a much more complex object. Even a cursory glance at media reports, personal accounts and health promotion materials reveal that PrEP is a number of things: a (daily) regimen of pills (that might be accompanied by side effects); a way of controlling one's own risk of HIV acquisition (rather than trusting others); a signifier of present and/or future HIV

risk; a supplement to, or replacement for, condoms; a marker of sexual excess; a pharmaceutical enhancement; an enabler of greater intimacy and of serodiscordant relationships; a way of bypassing difficult HIV disclosure discussions; and a powerful way of removing anxiety around HIV and sex.

PrEP can have unexpected meanings, and meanings that may only emerge in relations with others. What, for example, does PrEP make different about a sexual encounter between two HIV-negative men when one is on PrEP and the other is not? There are a numerous possibilities. PrEP can challenge the HIV-negative status of the non-PrEP-taking partner, rendering it less certain. Alternatively, PrEP can cause problems for the person doing the disclosing, in the sense that the other person understands PrEP use as being more 'risky'. Both these scenarios have been reported in interviews by gay men taking PrEP.

## Off-label PrEP

Although attention since 2011 has been concentrated on access to PrEP through demonstration projects – and more recently on the experiences of men accessing PrEP through these studies – I have become increasingly interested in PrEP outside these more formal arrangements. Previous surveys have indicated small numbers of gay men accessing ARVs for PrEP through importation, private prescribing within Australia, or through diversion of ARVs from people living with HIV. It is not known how many people are actually accessing ARVs in this way, but indications from social media, HIV organisations, and recent qualitative research, suggests that there has been a rapid increase alongside a general increase in awareness of PrEP. Given that the number of people involved in the PrEP demonstration projects is currently at 465 in total, the number of people accessing Truvada in other ways is likely to quickly exceed this, if it hasn't already.

There is very little formal research so far on the experiences and practices of people importing ARVs for PrEP (or diverting prescribed ARVs) and how the experiences and practices of men importing generic Truvada compare to those men accessing Truvada through demonstration projects in Australia. In addition to the meanings of PrEP already mentioned, some thoughts on relevant areas to explore are:

1) **People's experiences of accessing ARVs for PrEP.** What services do they use? Are there issues of affordability that prevent some people from using this option? How reliable are delivery times and supply continuity?
2) **Clinical guidance.** To what extent does the use of PrEP among gay men correspond to the recently drafted national guidelines? Is purchasing of ARVs undertaken in conjunction with a health-care provider? Is screening being undertaken prior to commencing ARVs? Are people attending for the recommended quarterly visits, including HIV and STI testing?
3) **Patterns of use.** Are people using PrEP on a daily dosing basis, or are they using it in different ways, i.e., intermittently, on an event-driven basis, or 'seasonally'? And if people are not taking it daily, is this primarily influenced by concerns about toxicity and side effects, self-assessment of only occasional risk of HIV acquisition, or for financial reasons (or indeed for all of these reasons).
4) **Efficacy/effectiveness.** Do people have confidence in ARVs for prevention (both in a general sense, and also specifically related to generic versions of the drug as opposed to brand-name Truvada)?
5) **Changes in behaviour and/or existing prevention strategies.** Does the use of condoms and other risk reduction strategies decrease after starting PrEP, or remain the same, or paradoxically increase, as it did in clinical trials?

## Pill talk

The recent *7.30* story was consistent with other recent media coverage on PrEP in the sense that it positioned the ARVs themselves centre stage. Most media stories on PrEP, including in social media, contain almost the exact same image, i.e. a person holding the pill between their thumb and finger, showing the GILEAD imprint (usually) or the 701 imprint on the other side. Other variations in health promotion materials include images of the pills alone, or spilling out of a bottle,

## The current situation in Australia

Clinical trials and observational studies have determined the efficacy and effectiveness of daily dosing of the antiretroviral combination drug (brand name Truvada) in dramatically reducing the risk of acquiring HIV. Truvada is a pre-existing drug that is used to treat HIV infection, however it is not licensed or subsidised for prevention in Australia. Truvada is only available for pre-exposure prophylaxis through 'demonstration projects' in Victoria and New South Wales (and soon in Queensland). Additional options for accessing Truvada for prophylactic use are through private off-label prescribing within Australia, and/or through importing generic versions of Truvada thorough online purchasing. The Australasian Society for HIV Medicine (ASHM) recently published guidelines on prescribing Truvada as pre-exposure prophylaxis for people at high risk of HIV.[3]

Earlier this year the manufacturer of Truvada made a TGA application, but the evaluation process could take 12 months or more, meaning that Truvada is not likely be listed for PrEP in the immediate future. A separate application would need to be made to the Pharmaceutical Benefits Advisory Committee (PBAC) to get subsidy through the PBS. Again, this is a lengthy process, although it could be commenced prior to an outcome from the TGA application.

PrEP can have unexpected meanings, and meanings that may only emerge in relations with others. What, for example, does PrEP make different about a sexual encounter between two HIV-negative men when one is on PrEP and the other is not?


PrEP health promotion campaign collateral from US-based Gay Men's Health Crisis (GMHC). The campaign features the now ubiquitous image of a person holding up a Truvada pill.

or interestingly out of a condom, without any link to the people who might be taking them. These images are a jolting reminder of how rarely we see images of ARVs anymore, and how paradoxical it is that images of ARVs now represent prevention rather than treatment.

It is already clear from repeat surveys conducted biennially since 2011 that those gay men who are the most willing to take PrEP are those who are also those who perceive themselves to be at highest risk[4,5]; and based on information available so far, it seems that a similar group of men have accessed PrEP through the demonstration projects.

Clinicians' (and other health care providers') attitudes to PrEP may be a significant barrier. Based on a study of people working in the HIV sector conducted in 2014, there was moderate agreement among participants that PrEP was effective (lower than for condoms and 'treatment as prevention') and participants reported that they were only moderately likely to recommend PrEP to gay men.[6]

Specifically among clinicians among in this sample, there were negative attitudes to providing PrEP because of the perceived costs (especially when compared to existing HIV prevention measures).[7] Some respondents explicitly framed provision of PrEP as subsidising gay men to have sex without condoms, and were for this reason uncomfortable with it as a strategy.[8] Clearly a great deal of work will need to be undertaken with this group to overcome these attitudes and for potential users of PrEP to be able to talk openly with their health care providers about it. There is a sense of urgency about this task too, because PrEP demonstrates how the boundaries of prevention are changing. Arguably, the most medicalised form of prevention to date can now also exist somewhat outside the control of medicine.

## Future

Demonstration projects and personal importation both offer only interim solutions (so not actual solutions) to providing ongoing access for those people already on PrEP and to making PrEP more available to others who would benefit from it – which would in turn have an important impact on the epidemic. The continued availability of Truvada for demonstration projects is uncertain, although an 18-month extension of supply for those people on the demonstration projects has created some breathing space for participants, especially those in Victoria who were in the last few weeks of their 12-month supply.

Also, the current negotiations in the Trans-Pacific Partnership agreement contain both positive and negative signals. On the one hand, future decisions by the Pharmaceutical Benefits Advisory Committee not to list a drug, or to list it subject to certain conditions, could be overturned.[9] On the other hand it is not hard to imagine pharmaceutical companies seeking to prevent importation of generic versions of ARVs if this prevents sales of brand-name drugs.

**Dean Murphy is currently conducting a study called Off Label on the experiences of gay men importing antiretrovirals for use as PrEP. For more information, or to take part, please email d.murphy@unsw.edu.au**

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There is a sense of urgency about this task too, because PrEP demonstrates how the boundaries of prevention are changing. Arguably, the most medicalised form of prevention to date can now also exist somewhat outside the control of medicine.

# Alan Brotherton (1963–2015)

By **Michael Hurley**

Elastic sided Blundstone boots,
Khaki shorts, a red truck and tales
Of derring-do on the foreshores of Botany.
Those were days of miracle and wonder.

*This is a long distance call.*

Alan Brotherton died of complications from melanoma on June 12, aged 51. He is survived by his partner Luke, by his parents, Alan and Doris, his brother Stephen, his sister-in-law Pauline, and his nieces, Isla and Kirsten. Friends and colleagues nationally and internationally have mourned his death.

Alan's family emigrated to Australia from the UK. He completed his secondary schooling in Canberra. Few people know Alan began his working life as a trainee chemical engineer in the Wollongong steelworks. I certainly didn't know that when I first met him. Most of us came to know him as a stalwart of the Australian and international responses to HIV and AIDS. When I visualise him he is either in those shorts and a blue singlet or a blue suit and business shirt.

Alan played a major role in organising the international AIDS conference in Vienna in 2010 as Director, Policy and Communication for the International AIDS Society (IAS), and its conference partners and co-sponsors. These partners included several UN agencies, the International Community of Women Living with HIV and the Global Network of People Living with HIV. Prior to that he worked for two years in the UK with the International HIV/AIDS Alliance travelling extensively to partner organisations in affected countries.

Susie McLean, a Senior Advisor at the Alliance and formerly of AFAO wrote that Alan, 'had an exquisite capacity to think deeply and differently, and to approach problems and dilemmas in HIV policy or programming with originality, drawing on the personal and avoiding generalisations and simplistic categories.'

In Australia, Alan was an activist in the early years of PLWHA (NSW), ACT UP and NAPWA. His activism was always linked to organised advocacy.

He worked for ACON initially in beats outreach, was President of NAPWA in 1996–1997, and then became the Education Manager at the Victorian AIDS Council/Gay Men's Health Centre. He returned to Sydney working briefly in policy at AFAO before becoming the first manager of the AFAO-NAPWA Education Team (ANET). He then managed education at the AIDS Council of South Australia.

In the early 2000s he returned to ACON as Client Services Director, and then went to work at NSW Health in policy before heading off to the Alliance in the UK as a Senior Advisor – first in Policy then in HIV Prevention. From there he went to IAS, working with Robin Gorna, a former executive director of AFAO. On his return to Australia he worked for ACON, this time in the role of Director, Policy, Strategy and Research.

On the day of Alan's death, Nicolas Parkhill, CEO of ACON wrote: 'Alan's commitment to promoting the health needs of women in our community, both internally and externally, cannot be understated [nor can] his work to ensure LGBTI people have a rightful place in ageing, mental health, drug and alcohol and healthcare. Alan could engage an audience like no other – always erudite and persuasive – and always delivered with … wit.'

I was first introduced to Alan when he was President of NAPWA. I met him, I think, through Scott Berry. Scott and Alan worked together on the national Positive Information and Education project. The work of ANET followed the earlier Gay Education Strategies (GES) teamwork of Ross Duffin, Paul Martin and Keith Gilbert. I had been an invited external advisor with GES and I worked closely with Alan in this time, first in ANET then as a Researcher in Residence. Somewhere in there he completed Honours and a Master's degree.

One of the things Alan and I had in common was the belief that if you are going to be an out gay man you might at least take the trouble to make something of it. Alan did.

As Kirsty Machon said in a recent conversation, 'Alan had a talent for living'. He liked good food and company and had eclectic tastes in music. He read widely, listened and thought. He partied. He was kind, generous, principled and compassionate. He was also mentally tough. Those sparkling blue eyes could pierce and sliver. Mostly they did so good-humouredly.

Ben Tunstall, a friend of Alan's in the UK, wrote poetically: 'Each stab of his blunt sonnet shoots out from beneath a curling lip and one eye narrows to see it land, usually exactly where he planned.'

Alan gave me two fridge magnets and at least one snow dome. The first magnet is of Dorothy's red shoes from *The Wizard of Oz*. He had remembered that when I was in Washington Dorothy's shoes were on tour and I had missed seeing them. The snow dome was from Patagonia. He knew I collected them and I recalled that as a much younger man he had gone to pick coffee as an international volunteer in Nicaragua. He believed in the struggle for justice occurring there and elsewhere in Latin America. He was well travelled and totally committed.

The second magnet is wicked, 'I used to care but now I take a pill for that.' Someone who didn't know Alan or hadn't lived and worked through the worst of the AIDS epidemic might read that magnet literally. It is anything but. In the defiant spirit of the early 1990s it is a multilayered, dark joke mixed with pain, mischief, insight, and irony. It is riddled with resilience. He cared, but like many

HIV activists Alan took empathy into another dimension, usually privately, because otherwise he was a public model of managed rectitude.

Alan made his own history out of personal and collective circumstance. Kirsty recounts a conversation in which he described coming to terms with his HIV status. He said he was standing against a wall in Spain eating a beautiful ripe peach and basking in the sun. He realised there and then that he could live in the moment with all its pleasures. He said he didn't remember a peach ever tasting as good, before then or after. Epiphanies however have a habit of reverberating long after a peach is finished.

As Bill O'Loughlin said at the funeral, 'He was, quite simply, an unforgettable marvellous presence.'

Pictured clockwise from top: Alan in Burgundy, 2013. Photo: Mathew Birch; Alan and Luke, Valentine's Day, Sydney, 2012. Photo: Jason Nichol Photography; (L–R) Alan, Elaine (ACON volunteer) and Nic Parkhill (ACON CEO); Alan the construction worker. Photo: Annie Marenghi-Collins.

**Michael Hurley is a friend and former colleague of Alan's.**

# Gay and bisexual men's attitudes to antiretroviral-based prevention

By **Martin Holt**

In 2011, the Centre for Social Research in Health began a program of work to investigate attitudes to biomedical HIV prevention technologies among gay and bisexual men, including HIV pre-exposure prophylaxis (PrEP) and treatment as prevention (TasP).

PrEP involves HIV-negative people regularly taking antiretroviral drugs to prevent infection with HIV. It has been shown to be efficacious in preventing HIV for gay and bisexual men, transgender women and heterosexual people at risk of HIV, although efficacy is highly dependent on drug adherence.[1] PrEP is not currently available in Australia as a subsidised medicine, although small demonstration projects began in three states in 2014.

HIV treatment as prevention is based on the finding that HIV-positive people who consistently take antiretroviral treatment and achieve viral suppression are highly unlikely to transmit HIV to their sexual partners.[2] Treatment as prevention is tacitly acknowledged in Australia's current National HIV Strategy, which emphasises the benefits of early diagnosis and treatment for people living with HIV, and the strategy acknowledges that PrEP may be useful for high risk populations (like gay and bisexual men).[3]

Why assess community attitudes to PrEP and TasP? Firstly, to know whether affected communities are interested in new prevention methods; there is not much point developing relatively expensive strategies (like PrEP) if people do not want to use them. Secondly, to identify who is most willing to use the new strategies, to see if there is an alignment between interest in using the strategies and potential public health benefit (i.e. do those who are at high risk of HIV want to use the strategies or not?) Thirdly, research can gauge community support, to see if those who use biomedical prevention strategies will be supported by others. For example, at this stage, it is unlikely that many HIV-negative gay men will use PrEP in Australia, as it is a relatively costly intervention and the risk of infection is concentrated among a relatively small group of men.[4] However, for PrEP to be successful and become an accepted part of gay and bisexual men's sexual practices, arguably you need broad levels of support, including among those men who might never use PrEP.

When we started our research, the first area we looked at was gay and bisexual men's attitudes to PrEP. We conducted national, online surveys in 2011 and 2013 (and we have just finished recruitment for 2015, although at the time of writing we were still working on the results). In 2011, we found that 28% of HIV-negative and untested gay and bisexual men were willing to use PrEP.[5] This was a much lower level of interest in PrEP than had been seen before in international studies[6], particularly those from the United States, but our measure of willingness to use PrEP took into account readiness to regularly take pills, that PrEP might not be 100% effective and that you might have to pay for the drug. In 2013, willingness to use PrEP fell slightly to 23%.[7]

It is far from clear why willingness to use PrEP declined between 2011 and 2013; it is possible that as knowledge of PrEP has grown, interest in it has become more concentrated among gay and bisexual men who find it acceptable, while other men have decided it is unsuitable for them. We are very keen to see what has happened this year, given that there has been a lot more media coverage about PrEP since the Australian demonstration projects began.

Although willingness to use PrEP appears to have declined between 2011 and 2013, the profile of men who are most interested in using it appears to have remained largely unchanged. In 2011, we found that willingness to use PrEP was concentrated among younger men, those who had anal intercourse without condoms with casual partners, men who perceived themselves to be at risk of HIV, and those who had fewer concerns about side effects.[8] In 2013, we found a similar profile; younger men, those who had HIV-positive partners, men who perceived themselves to be at risk of HIV, who had previously taken post-exposure prophylaxis (PEP) or had fewer concerns about side effects were the most interested in using PrEP.[9] So although willingness to use PrEP declined a little, it remained concentrated among HIV-negative and untested men at increased risk of HIV.

These findings show that the targeted rollout of PrEP is feasible in Australia, because there is a minority of gay and

bisexual who are interested in using PrEP and who would benefit from its protection. This appears to be borne out by the rapid uptake of places in the demonstration projects in Victoria and New South Wales by gay and bisexual men at high risk of HIV.

The other major area that we looked at our surveys was attitudes to HIV treatments and TasP. In general, we have found that gay and bisexual men are positive about the health benefits of HIV treatments.[10,11] However, in both 2011 and 2013 we found that participants were highly sceptical about the preventative benefits of HIV treatments and they were unlikely to believe that having an undetectable viral load prevented transmission. HIV-positive men appeared to be slightly less sceptical than HIV-negative men, but it was clear that community attitudes to TasP were far from optimistic.

In 2013, we included a range of additional items about HIV treatment and found an interesting contradiction.[12] While very few men believed that HIV treatment prevented transmission (<3%), a large majority (72%) agreed that early treatment was necessary. Why this apparent contradiction? We think that this is because most gay and bisexual men understand the health benefits of HIV treatment but they view TasP as an unproven or unreliable strategy for prevention.

In addition, an interesting qualification emerged when we looked at whether HIV status affected men's attitudes. HIV-positive men and men with HIV-positive partners were a little more likely than others to believe in TasP, but they were less likely to agree with the need for early treatment. Why might that be the case? We think that this is because HIV-positive men and their partners are more aware of the risks and benefits of starting treatment, and they may be reticent about being encouraged to take treatment without a full consideration of these factors. This is consistent with research conducted with HIV-positive people and HIV doctors which emphasises that decisions to commence treatment should be driven by the need to maximise individual wellbeing, and not determined solely by public health concerns.[13,14]

So far the research we have conducted suggests that there is support for the introduction of PrEP in Australia, particularly among gay and bisexual men who appear to be at high risk of HIV. Views of HIV treatment as prevention are more mixed, with belief in the health benefits of HIV treatment, but continuing scepticism about TasP. Our research suggests that promoting the health benefits of treatment appears to be a more acceptable way to promote TasP to gay and bisexual men, rather than emphasising its preventative benefits. However, in doing so we should be careful not to imply that HIV-positive men must go on treatment to benefit others; this violates beliefs that HIV-positive people should be free to make treatment decisions that are appropriate for their particular circumstances, supported by their partners and doctors.

**For more information about the PrEPARE Project visit: http://prepareproject.csrh.org**

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PrEP involves HIV-negative people regularly taking antiretroviral drugs to prevent infection with HIV. It has been shown to be efficacious in preventing HIV for gay and bisexual men, transgender women and heterosexual people at risk of HIV, although efficacy is highly dependent on drug adherence.

# Why might some people with HIV feel concerned about using treatment as prevention?

By **Christy Newman, John de Wit, Asha Persson, Martin Holt, Limin Mao, Sean Slavin and Michael Kidd**

The more than thirty year history of HIV medicine has featured dramatic successes and controversies. While contemporary research continues to break new ground across many different areas, much of the policy and community debate regarding the science of HIV medicine has become focused on when and why to make use of antiretroviral therapy (ART). As outlined in a number of articles in this issue of *HIV Australia*, the details involved in translating clinical trial successes in this area into feasible and acceptable 'real world' practices remain confoundingly complex.

One of the major new features of the changing landscape of HIV medicine is HIV treatment as prevention (TasP). The implementation of TasP is being shaped by the still relatively new evidence from randomised controlled trials that the use of ART to reduce HIV viral load to undetectable can dramatically reduce the risk of sexual transmission of HIV. Many clinicians, governments and advocacy organisations in Australia and elsewhere have now taken up strong and aligned positions by recommending all people with HIV use ART as early as possible, to prevent the risk of both individual illness and onward transmission posed by 'untreated' HIV infection.[1] Yet the personal and situated insights of those asked to take these medications daily, as prescribed, and for the rest of their lives, have been largely absent from these debates. In particular, little has been heard from the perspective of those who hold concerns regarding the increasingly central role of medications in managing both the individual and community impacts of HIV in Australia.

As part of a broader study on ART initiation, from 2012 to 2014 we conducted semi-structured interviews with 27 people living with HIV around Australia who were not using treatment at the time of interview. Our research was particularly interested in understanding why some people with HIV may feel concerned about using treatment, including for HIV prevention. While the dissemination of results is ongoing, three initial publications reported a number of findings which we hope will contribute to broadening the debate regarding the acceptability of treatment – and of treatment as prevention – across the diversity of people living with HIV.[2,3,4] In this article we summarise some of the emerging lessons from this research.

As background, it is essential to recognise that while work continues on estimating the number of people with HIV who are not currently using ART[5], this is a minority of people living with HIV in the

Australian context. Our interviews with members of that group also suggest very few are in conflict with medical providers on the issue of using ART.[6] Most people with HIV who are not currently using treatment have either been diagnosed only recently, are not able to use these medications for other health reasons, or have a prescribing doctor who is cautious about recommending initiation when not yet deemed essential.[7] This doesn't mean these individuals don't hold any concerns or fears about the use of ART, but it does mean they are open to the possibility of starting when the time is 'right' despite these doubts.

Along with recognising that most people with HIV are currently using ART, it is also important to appreciate that many feel greatly reassured that effective treatment has been shown to dramatically reduce the risk of inadvertently transmitting HIV to sexual partners[8], in addition to providing benefits for their own health. However, in our research with non-ART users we observed very high levels of awareness of, yet little support for, the use of ART to prevent transmission to others[9]. Instead, participants expressed a number of recurring concerns about this strategy.

Concerns focused on perceived tensions regarding who would benefit from TasP – the person taking the medication, or the government responsible for reducing infections, for example – and questions about whether TasP would encourage an over-reliance on or over-valuing of treatment above other risk reduction strategies.[10] As a gay man who was ART naïve but open to commencing treatment put it:

> *'From what I [understand], they want to, and quite rightly so, lower the infection rates throughout the country and … the more people that can go on medication, the lower the viral loads will become to undetectable, the less infectious they will become and this in turn can lower the infection rates. But throughout talking with other people, some of us, not all of us, but some people have come to the conclusion that … it's not a good enough reason for someone to go on medication and potentially risk their health … People should be on medication … for their own health, not for political reasons … I would much rather go along the lines of either abstinence or protected sex or no risk sex, rather than go on HIV medication … No, for me [the decision to start treatment would be] for health reasons purely.'*
>
> — Simon: gay man, 40s, born in English speaking overseas country.

As emphasised in this quote, many participants were concerned that TasP assumed that the only reliable or responsible way to mitigate the risk of transmitting HIV is to engage fully with biomedical approaches to prevention, which can (perhaps inadvertently) lead to some people with HIV feeling they are not trusted to modify their behaviour in other ways to reduce risk. Other concerns were expressed regarding a perceived shift in treatment norms as policy support increased for early initiation and treatment as prevention. In a troubling development, a number of participants believed that since TasP principles began to be emphasised in HIV policy, notably less support and encouragement was provided in clinical and community settings for open and honest conversations about the doubts and fears some people hold about medication use in general, and ART in particular.[11]

We know the concept of citizenship in liberal democracies such as Australia incorporates the expectation that individuals take personal responsibility for all key life decisions, particularly those involving health.[12] This expectation needs to be complemented by support for those who are engaged in practices of thinking carefully and critically about important health decisions, and to actively encourage conversations with those who feel unsure about how to resolve their fears about the potential risks of taking medicines. Given that treatment as prevention is markedly extending the range of possible benefits of and complexities in making treatment decisions today, providing an appropriately expansive and supportive environment for community discussion is surely even more necessary at this point in the epidemic.

As we have also observed in our research, people with HIV may have very sound reasons for not placing their trust in medicine: they know there are potential harms, they know they risk developing resistance, they know that science cannot tell them what the effects will be of using ART over a very long period.[13] People with HIV also know that some of the greatest advances in the field also caused significant harm to those who were early adopters, and uncertainty lingers regarding the risks of jumping on to another pharmaceutical 'rollercoaster'.[14] Thus, while many would argue there is sufficient evidence available today regarding the safety and effectiveness of ART to counter any lingering doubts among potential consumers, reluctance to engage in a lifelong HIV treatment regimen is influenced by a far more complex and interrelated set of factors than simply awareness and appreciation of the potential benefits.

The process of making decisions about medication use is always shaped by individual history and circumstances. Since HIV treatment is a lifelong, daily practice, even if doubts are resolved, they may re-emerge over time, with ART involving, at a minimum, a once-a-day commitment to a lifelong therapeutic plan. Our participants defended their right to

Concerns focused on perceived tensions regarding who would benefit from TasP – the person taking the medication, or the government responsible for reducing infections, for example – and questions about whether TasP would encourage an over-reliance on or over-valuing of treatment above other risk reduction strategies.

make treatment decisions carefully and based on their own unique circumstances and trajectories, without undue pressure or coercion from peers or prescribers, or the presumption that they needed to simply accept the evidence for commencing ART as clear and uncontroversial. Opportunities for safe, supported dialogue and the exchange of peer accounts of the experience of treatment can reassure those with doubts, and comfort those who find the challenges and complexities of treatment significant. Thus, encouraging open conversations in clinical, community and policy contexts about these diverse perspectives will be essential in engendering public trust in a new era of treatment and prevention.

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Photo: Cec Busby.
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# Strength in numbers: The Institute of Many (TIM)

By **Nic Holas**

*'When I was diagnosed TIM did not exist and for five years I went on with life not knowing other people in the same situation. Now this sense of community has given us a cause and has, for me at least, broken down that sense of isolation.'*

— TIM Member, 2015

In just two years, The Institute of Many (TIM) – a peer run social network and advocacy platform for people living with HIV (PLHIV) – has grown from a tiny collective of poz gay men communicating via email group, to being recognised as major player in Australia's HIV landscape.

While TIM may represent a new model for engaging people living with HIV, it is by no means intended to substitute the work of established agencies, organisations and services across Australia. Our aim is to work with these organisations, not against them.

The landscape of PLHIV community representation and support is shifting. The pressure for this shift is coming from above, as funders drive service delivery into a world of competitive tenders, and from below, as the needs of the PLHIV community become more diverse. How the HIV sector responds to these pressures will either ensure Australia's continued leadership on HIV, or cement this author's fear that Australia may rest on the laurels of triumphs past.

## TIM's history

*'I never had my shit together with my HIV before TIM, no support, no camaraderie, no mentors, and I was under-informed … being amongst you all has changed that and subsequently changed me for the better/stronger.'*

— TIM Member, 2015

TIM began – rather fittingly for an origin story – at a Genesis workshop in November 2012. ACON/Positive Life NSW co-delivers this weekend workshop for newly diagnosed HIV-positive gay men. I was only a few weeks into my HIV diagnosis, as was fellow participant, an American man named Jeff Lange. Jeff and I bonded over the relative ease with which we dealt with our new status.

At the end of the workshop, Jeff wanted to know what was next. Where did poz men go to meet, ask each other questions and share stories?, he asked. The answer, 'There really isn't anywhere,' didn't satisfy him. Jeff had started a social group for gay men in his native and deeply homophobic South Carolina and thought something similar for poz men might work in Sydney.

Meanwhile, at three weeks into my diagnosis I already had an overwhelming feeling that I had something important to say about HIV. My relative ease with being diagnosed HIV-positive meant I felt a responsibility to those who didn't get such a comfortable ride. I didn't want anyone to be ashamed of his or her HIV status, and neither did Jeff. So, with the dual purpose of increasing community engagement and political awareness in mind, we started TIM.

From the very start, ACON was excited by what we were trying to do and offered to help any way they could – without actually owning TIM. In order to be successful, ACON recognised that we had to be completely community owned and free from any 'sector' influence. This 'hands-off' approach to support continues to this day, and has extended to a number of other AIDS Councils and PLHIV organisations who have been involved with our work. TIM would not be as successful as it is without this approach.

By April 2013, we'd hosted a couple of events but had begun to realise that our group email approach to communications was becoming rather cumbersome and one-sided. Inspired by the old adage of HIV promotion: 'go where they already are, don't ask them to come to you,' we looked to social media and set up TIM as a private group on Facebook. I laugh now, recalling the early days when we only had a dozen or so members and I'd have to post articles every couple of days to try and encourage discussion.

## TIM today

> *'I have learnt that everyone's journey is different, each story unique, but we have one, common thread that binds us all together. I value the thoughtful debate, support, conversation and differences of opinion.'*
>
> — TIM Member, 2015

Today, the TIM Facebook group has almost 1,000 members from around Australia and overseas. This digital gathering space has fostered the development of meet-up chapters in Sydney, Melbourne, Brisbane, Adelaide, and Perth, and inspired similar digital/meet-up groups in New Zealand and Japan.

Members identify as gay, straight (men and women), bisexual (men and women), cisgender, transgender, intersex, and queer. The vast majority are in Australia, but we also have members in New Zealand, USA, Canada, UK, Europe, Mexico, Malaysia, Singapore, Japan, Hong Kong, the Middle East, South America and Africa.

TIM's international membership, as well as our sexual and gender diversity, provides a variety of voices on HIV. Not to mention some much-needed perspective for those who sit atop the 'pyramid' of HIV privilege.

TIM's digital space allows members to ask questions about HIV, post articles, and generally engage with their peers. Topics such as stigma, disclosure, sex and dating, treatment uptake and side effects, criminalisation, lived experience, AIDS history and survivor trauma all come up regularly.

The most frequently asked question tends to be: 'Anyone else experiencing "X side effect from X meds?"' I'm proud to say that numerous members have been motivated to change their treatment regime after realising they didn't have to accept certain side effects as just 'part of being HIV+'.

I make no bones about how we moderate the TIM group. We've had a vision for TIM since day one, and that vision has always been expressed on the page. Over time, as issues came up, we established a posting guide that covers everything from the classic, 'use "I" statements,' to attempting to curb the seemingly endless pool of negativity we can draw on as people living with HIV, and instead encouraging members to focus on more positive and proactive ways to address issues.

## TIM's values

At the end of 2014, TIM was turning two and the tone of the Facebook group was going the way of so much HIV discourse: victim mentality, petty arguments, some sector interference, and generations of bad blood had created a tense, toxic environment that saw some long-term members walk. With that in mind, we conducted a survey of TIM members to establish the group's values. It has been a turning point in the way TIM is managed.

Over one-third of our members completed the online survey, the results of which were shared within the group to establish a firm point of the view about the organisation and its values. It's important to note that anyone who disagrees with these values is still welcome to be a part of TIM; however, when discussions turn into arguments (an unfortunate by-product of any online discourse), these pre-established values help draw a line underneath what could otherwise be endless threads that quickly become personal.

TIM's values cover issues like lived experience, generational points of difference, the inclusion of women and gender diverse PLHIV, drug use, sex work, condoms, PrEP (pre-exposure prophylaxis) and TasP (treatment as prevention), criminalisation, resilience, disclosure, and living openly as an HIV-positive person.

TIM's values cover issues like lived experience, generational points of difference, the inclusion of women and gender diverse PLHIV, drug use, sex work, condoms, PrEP (pre-exposure prophylaxis) and TasP (treatment as prevention), criminalisation, resilience, disclosure, and living openly as an HIV-positive person.

Part of TIM's success has been based on bringing together HIV-positive people with very diverse opinions, and we want to continue to encourage that diversity. We acknowledge that there is no perfect answer that represents the views of all people living with HIV, all of the time. However, we have unashamedly set our sights on moving the community forward. Enabling a culture of endless arguments without an overarching sense of purpose contributes nothing to the community but hot air.

In April of this year, one of the women in TIM approached us about setting up a TIM Women space on Facebook. Like the main TIM group, TIM Women is an experiment that relies on its membership to stay alive. Our hope is TIM Women will use the TIM model of community engagement, and our forward-facing values, to provide HIV-positive women with a new space to connect.

## TIM's advocacy

With TIM's community engagement strategy now firmly established, we are also moving into the advocacy space. We've just launched a harm reduction resource aimed at HIV-positive gay men who use crystal meth, the final result of a nine-month collaboration with Living Positive Victoria. We have also put our name to the Victorian AIDS Council's #ApprovePrEPDownunder campaign.

We have contributed to policy documents for political parties, and regularly provide media with public-facing members who speak to their lived experience as people living with HIV. The ongoing community dialogues taking place in the TIM space continuously inform our advocacy.

## TIM's challenges

*'I love meeting people just as passionate to make a difference in my community.'*

— TIM Member, 2015

TIM is an experiment in community organising, and much of that experiment has been a baptism by fire. We've certainly overshot the mark as moderators in the online space, sometimes being too heavy-handed and other times, too lenient. Establishing a code of conduct that can speak to the highly individualistic experience of people living with HIV has resulted in members leaving the group, sometimes after a heated debate.

We recognise that TIM is not for everyone, nor can it be. The larger we grow, the more diverse the opinions, and the less likely it is everyone will agree with our vision or values. What's vital is that we keep scrutinising our vision to ensure it remains current and responsive, ensuring that we don't bend to the will of those who oppose it just to keep our membership numbers spiking.

As TIM grows by the day, our survival is dependent on establishing a sustainable model of financial and political independence, whilst still working in partnership with established organisations.

What we must not become is genuine competition. We are not interested in the competitive tenders that already threaten to see the sector pitting agency against agency – quite honestly, we're not equipped to deliver services to high needs clients. Nor are we interested.

It seems must make that stance better known though. TIM was identified in a recent National Association of People Living with HIV (NAPWHA) member's survey as a competitive threat. This is clearly an issue, as all our collaborative efforts with HIV organisations have been (to date) highly successful.

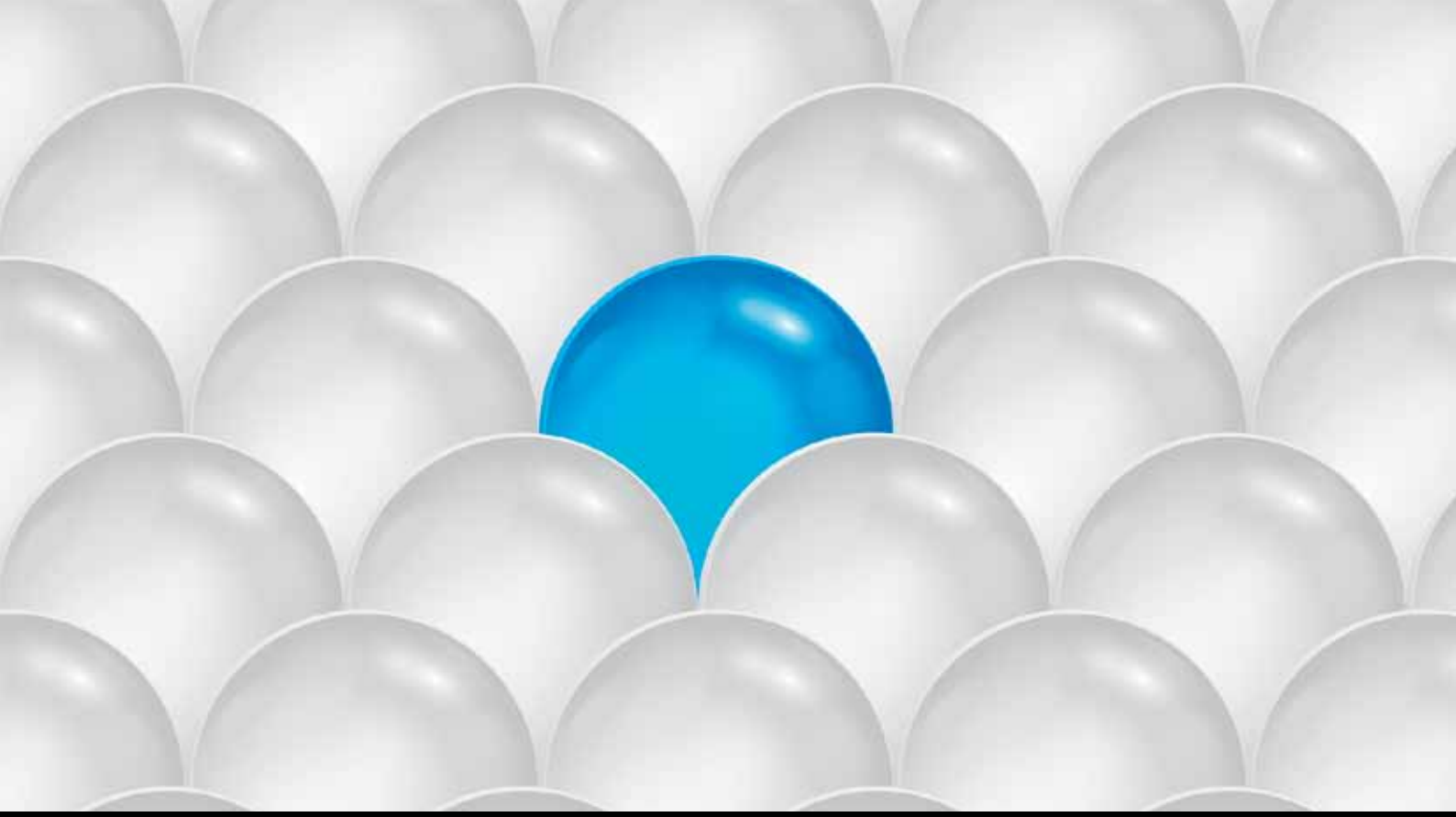
## TIM tomorrow

If you asked me 18 months ago what TIM would look like mid-2015, I couldn't have predicted it. I hope as governments make greater demands on organisations to do more with less, TIM can continue to work alongside those service providers and support their long history of engagement with people living with HIV.

Should we be unable to sustain financial support or community endorsement, my hope is that the TIM model can be used for future endeavours in engagement with HIV-positive people in Australia and abroad. TIM by no means reinvented the wheel when it comes to community engagement, but what we've managed to achieve thus far is palpable. I, for one, think we're just getting started.

**For further information about TIM visit: www.theinstituteofmany.org**

**Nic Holas is a freelance writer, HIV activist, and co-founder of The Institute of Many.**



# Biomedical prevention of HIV and sex workers

By **Cameron Cox, Joel Falcon and Gemma Keegan**

Scarlet Alliance, the Australian Sex Workers Association, is the peak national sex worker organisation in Australia. Formed in 1989, the organisation represents a membership of individual sex workers and sex worker organisations. While the legal and political context of sex work differs from state to state, and between nations, sex workers as a community share concern for the direction of biomedical prevention, and the need to guarantee the future of existing prevention strategies that have proven effective for sex worker communities.

Sex worker communities haven't been central to the conversation on the appropriateness of biomedical prevention for our community.

Sex workers continue to support increased access to HIV treatment and prevention options, including biomedical interventions, but with the understanding that these may not be suitable for use by all sex workers – especially given the success of proven prevention strategies already employed by sex workers, including community engagement, peer-led outreach, and policy advocacy addressing stigma, discrimination and enabling legal environments. That's not to say that biomedical interventions are of no benefit to sex workers. There may be benefits for individual sex workers living with HIV, for example, but a 'one-size-fits-all' approach is extremely problematic.

Sex workers in Australia have a long and complicated history of criminalisation, stigma, and discrimination by governments and communities, and have been subject to various policies under misguided public health responses that breach sex workers' human rights and undermine sex workers' agency. Decriminalisation of sex work, our workplaces and our clients remains the number one priority for sex worker communities and organisations, and an integral part of maintaining the low prevalence of sexually transmissible infections (STIs) and HIV among sex workers in Australia.[1]

## Pre-Exposure Prophylaxis

Scarlet Alliance's position on pre-exposure prophylaxis (PrEP) comes out of broad national and global community consultation – in particular, the Global Network of Sex Work Projects (NSWP) consultation on PrEP and early treatment: 440 participants from 40 countries participated in this consultation through 20 focus group discussions, 146 key informant interviews, and 33 online surveys, with the Australian component of the consultation conducted by Scarlet Alliance. All this work informs our stance on PrEP.[2]

Sex worker community-led approaches to prevention – including community engagement, peer education and outreach – have demonstrated their effectiveness over the last 30 years. We recognise the potential positive impacts of PrEP for some communities, but are concerned about the lack of consultation with sex workers on the usefulness and effectiveness of PrEP for sex workers, the future of biomedical HIV intervention and how this will impact sex workers, and the potential for PrEP to be prioritised at the expense of other proven HIV and STI prevention strategies currently used by sex work communities.

Studies on PrEP's effectiveness have been mostly among men who have sex with men, not trans and gender diverse, male and female sex workers.

PrEP is considered unsuitable as a primary method of safer sex for sex workers, as it only prevents HIV. The need to prevent all STIs remains an important part of health and safety for sex workers. Focusing solely on HIV prevention detracts from proven safer sex approaches that include all STIs and overall sexual health. Sex workers have lower rates of HIV and STI transmission than the non sex working public, due to community-based, sex worker led prevention programs and a broad culture of condom use. Generic PrEP campaigns suggest (even by omission) that PrEP is an effective HIV prevention approach for all affected communities, and fail to acknowledge that sex workers' strategies combine HIV and STI prevention as part of a holistic approach.

Sex workers have long been (incorrectly) assumed to be vectors of disease. This has led to criminalisation of sex work, mandatory testing and other failed health approaches that are neither human rights nor evidence based. Promoting PrEP as the most effective HIV prevention strategy, without educating sex work business owners and governments on the reasons it may not be appropriate for sex workers, leaves sex workers vulnerable to misguided policy decisions and workplace violations. Sex workers already have high rates of voluntary testing, and low prevalence of STIs; any health initiative or HIV prevention approach, including PrEP, must be voluntary.

## Treatment as prevention

Several of the concerns sex workers have about PrEP apply equally to treatment as prevention (TasP). While research continues to demonstrate that people with HIV who have suppressed or undetectable HIV viral loads are far less likely to transmit HIV, Scarlet Alliance and sex workers generally are concerned that the research thus far is not comprehensive enough for sex workers to rely on TasP as a new HIV prevention model.

The research on TasP has not clearly established that a person with a low viral load can be considered completely not infectious, or that a viral load test is a true indicator of infectiousness through sexual fluids. The presence of STIs may also increase the likelihood of HIV transmission or acquisition. Research also cannot predict if people in good health will adhere to the treatment program long term or what other behavioural prevention strategies might be abandoned long term, increasing infectiousness. There is also a concern that the outcome of trials involving gay men and men who have sex with men are being applied to sex worker communities.

There are barriers to accessing testing, treatment and health services, especially for sex workers who are criminalised. In states where HIV-positive sex workers are criminalised, states with mandatory testing, or in places where free, anonymous voluntary testing is inaccessible or difficult to access, sex workers may be reluctant or unable to be tested. The stigma and discrimination routinely faced by sex workers may also result in poor or disrupted access to treatment, affecting capacity to adhere to the required treatment schedule and potentially affecting the effectiveness of TasP. The stigma and discrimination that sex workers face impact the ability to access testing and treatment, and thus to adhere to treatment long-term.

Scarlet Alliance is also concerned that the promotion of TasP as suited to all communities could lead to compulsory or coercive testing and treatment policies used against or aimed at sex workers. This is not an unlikely eventuality in light of the mandatory testing of sex workers in some Australian states and internationally. Sex workers living with HIV, particularly where the person is also using drugs or has mental health issues, have been managed by public health committees where there wasn't a need for them to be.

There are human rights implications if non-voluntary use of PrEP or TasP were to be seen as an appropriate public health measure by governments or committees who manage people who put others at risk.

As with PrEP, sex workers are concerned that a push for TasP could eclipse current STI prevention strategies, which have been effective in preventing HIV and STI transmission in sex worker communities for 30 years. TasP could also negatively impact the ability of sex workers to negotiate safer sex with clients.

## Rapid testing

Rapid testing has the potential to lower barriers to testing for some communities and groups of marginalised people; however, it also has the potential to be abused and used against those same communities. As a low prevalence population with high levels of voluntary testing, sex workers should not be targeted for rapid testing as the likelihood of false positives is high.[3] Health care providers should not be incentivised to target sex workers.

Furthermore, Scarlet Alliance does not support the use of rapid testing where sex workers could be unfairly targeted, criminalised, stigmatised, discriminated against or forced to undergo testing that breaches their privacy or violates their human rights. In jurisdictions where sex workers working with HIV or an STI are criminalised, rapid testing can be rapid criminalisation, making workers liable for prosecution and compromising sex workers' careers, incomes and lives.[4] This

We recognise the potential positive impacts of PrEP for some communities, but are concerned about the lack of consultation with sex workers on the usefulness and effectiveness of PrEP for sex workers, the future of biomedical HIV intervention and how this will impact sex workers, and the potential for PrEP to be prioritised at the expense of other proven HIV and STI prevention strategies currently used by sex work communities.

is particularly concerning where testing is combined with contact tracing. Sex workers must be able to access testing in a way that does not breach their privacy or allow them to be publically vilified.

Apart from the fact that the risk of false positives should preclude targeting sex workers for rapid testing, rapid testing in sex workers' workplaces would compromise the privacy and livelihood of sex workers. Employers may coerce workers into being tested in the workplace under threat of their jobs being terminated if they refuse. Testing must always be voluntary; no sex worker should be coerced or compelled to undergo rapid testing. Voluntary, confidential, anonymous and patient-initiated testing remains the best-practice approach to STI and HIV testing, in keeping with the National Strategies.

## Conclusion

It is clear, from years of research and the first-hand experience of sex workers, that the most effective means of improving the health and safety of sex workers is decriminalisation of sex work. From *The Lancet* series on sex work, 'across both generalised and concentrated HIV epidemics' it was determined that decriminalisation would 'have the largest effect on the course of the HIV epidemic' in preventing HIV transmission for sex worker communities.[5,6]

New HIV prevention techniques cannot be considered a substitute for community engagement, provision of safer sex supplies combined with peer education strategies on how to negotiate their use, or community-led health promotion. They are not an alternative to evidence and human rights based health approaches and should not redirect funding from proven, effective approaches implemented by sex worker organisations.

As the conversation surrounding biomedical intervention and sex work continues, it is imperative that sex workers are consulted about the potential repercussions of biomedical interventions for sex workers in Australia and internationally.

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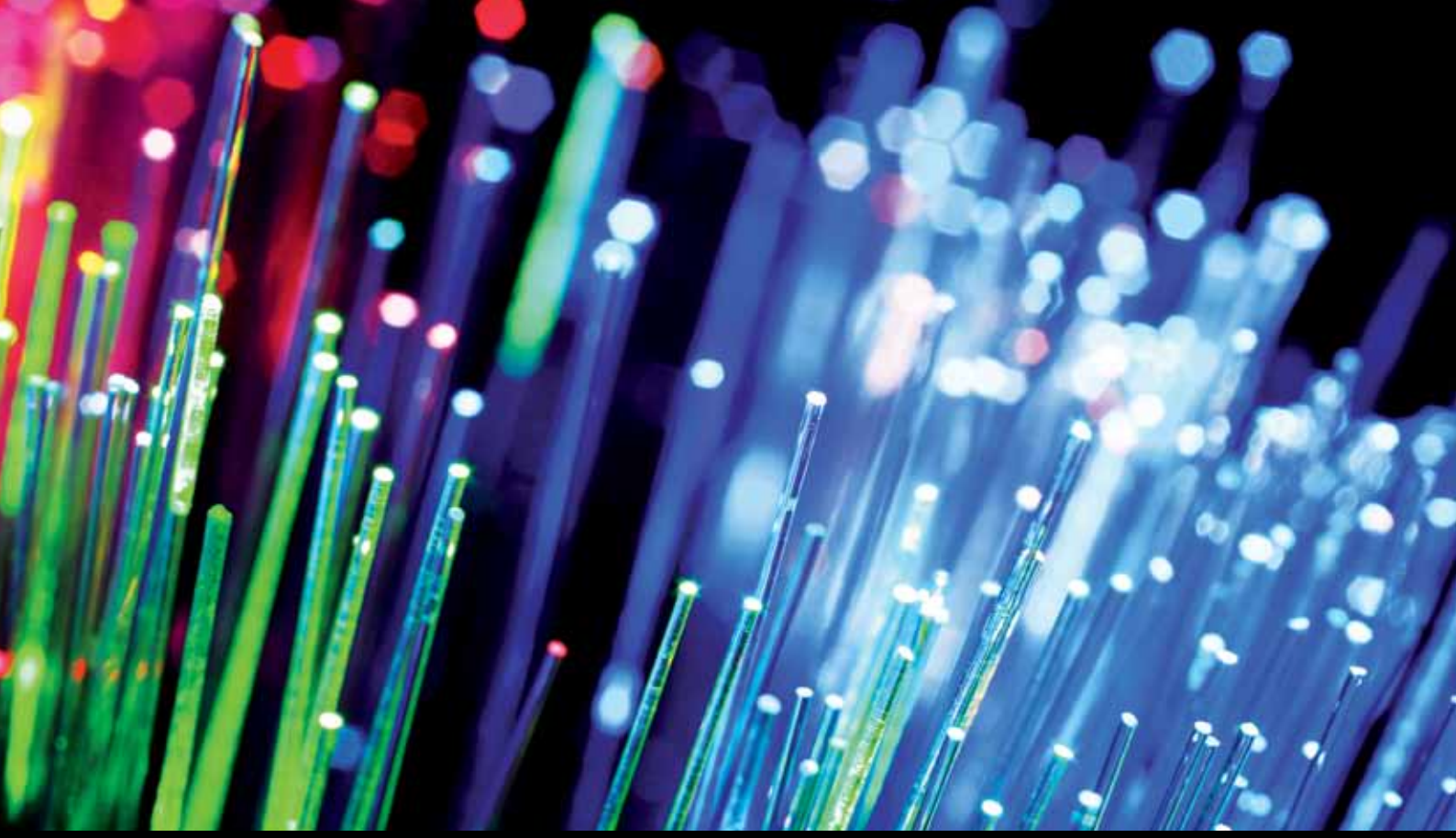

# Microbicides and HIV prevention in women: the state of research

By **Jennifer Power**

Earlier this year in Seattle Washington, participants at the Conference on Retroviruses and Opportunistic Infections eagerly awaited the first public announcement of results from the FACTS 001 microbicide trial.

The FACTS 001 trial – named after the Follow-on African Consortium for Tenofovir Studies (FACTS)[1] who were running the trial – was a large-scale clinical trial of a microbicide gel containing the antiretroviral drug tenofovir.

The FACTS 001 trial involved over 2000 HIV-negative young women from South Africa. Each participant was randomly assigned to the intervention group (receiving the tenofovir gel) or the control group (receiving a placebo gel). Participants were asked to insert the gel into their vagina prior to and after sexual intercourse while continuing their usual safe-sex and contraceptive methods. Unfortunately, over the course of the trial, which ran from October 2011 until August 2014, 123 participants acquired HIV and there was no difference in the rate of new HIV infections in the tenofovir gel group compared with the placebo group. This was a disappointing result.

Microbicides are products, usually a gel or cream, inserted into the vagina or rectum prior to, and after, sex to help reduce the risk of HIV infection. Microbicide research been strongly encouraged by women's health advocates because – if proven to be effective – it offers an HIV prevention method over which women would have control. Unlike condoms, microbicides do not need consent or cooperation from a male sexual partner; the male partner may not even know a microbicide is being used. In countries where there are numerous cultural barriers to condom use, or where women may have less power or capacity to insist on safe sex, products such as microbicides could become central to reducing HIV transmission rates.

## But, do microbicides work?

The idea for an HIV microbicide was inspired by the spermicide product Nonoxynol-9 (N-9), the active ingredient in many contraceptive gels. However, trials of N-9 for HIV prevention conducted back in the mid-1990s indicated that not only did N-9 not prevent HIV, it actually made women more susceptible to HIV infection by stripping away natural barriers within the vagina. Following this, trials for other forms of microbicides, including products which aimed to create a barrier around target cells or strengthen natural defences within the vagina, have not proven to be effective.

However, the latest generation of microbicides, which contain antiretroviral drugs such as tenofovir, appear to be more clinically effective. These microbicides work by preventing HIV from reproducing and establishing an infection if it enters the body.

A trial conducted in South Africa between 2007 and 2009, the CAPRISA 004 trial, found tenofovir gel reduced the rate of HIV infection among women by 39%.[2]

These results have not been replicated in larger studies. The VOICE trial (short for the Vaginal and Oral Interventions to Control the Epidemic) was a major trial

of tenofovir gel conducted across Uganda, South Africa and Zimbabwe between 2009 and 2011.[3] Similar to the FACTS 001 trial, the VOICE study found no difference in HIV infection rates between women using tenofovir gel and those using the placebo. This was not necessarily because the tenofovir gel did not work from a clinical or biomedical perspective. Rather, neither of these studies could demonstrate efficacy of the gel because many women enrolled in the trials simply did not use it. In the VOICE trial, the average rate of adherence to the gel was only 25%.[4]

In both trials, HIV infection rates were lower among women who used the gel consistently, suggesting that it does work if used properly. However, it is difficult to verify if this group were at less risk of HIV for other reasons. Possibly those who managed to use the gel consistently also had other structures or supports in their life which helped them negotiate safe sex. More research is needed before tenofovir gel can be approved for distribution.

The findings of FACTS and VOICE highlight the need for greater community education around biomedical prevention methods, and arguably, the need for study design that is more sensitive to the pervasive impacts of HIV stigma and of women's needs.

## A social or clinical problem?

Investigators on the VOICE study conducted interviews with research participants to explore socio-cultural factors which made adherence to microbicide gels difficult or undesirable for women.[5] Interviews were conducted with around 300 women, focusing on their experiences, behaviours, beliefs and attitudes about HIV risk and ARV-based prevention, and on their relationships with trial staff.

Many women said that they found it hard to coordinate use of the gels with their schedule, often being at work or school at the time they were required to insert it, either before or after sex. Other women did not use the gel because their partner did not like the feel of it, or because he did not support her participation in the trial.[6]

There was a strong sense of ambivalence and in some cases mistrust of the research among participants. Many women were convinced the gel would harm their fertility or make them ill; or they worried that researchers would actually infect them with HIV as part of the study, a view reinforced for some women by their partners, friends or family. Stigma was also a major issue. Women did not want to be associated with a trial or a product that might lead others to assume they were HIV positive.[7]

Armed with these research findings, investigators on the FACTS 001 trial put in place an intensive program to support adherence. This involved client-centred counselling, motivational text messages and monthly social clubs for participants. Unfortunately, this did not translate into higher levels of adherence.

So at this point in time, the question of whether or not microbicides are effective is largely social, not clinical. What social and cultural supports would help women use a microbicide gel if one was available? Or is it simply unrealistic to expect there would ever be widespread uptake of this type of product?

## The way forward

Oral pre-exposure prophylaxis (PrEP), taken once per day, may be easier for some women to manage than microbicide gels. However, trials of oral PrEP in real-world settings have encountered similarly low rates of adherence to that seen in microbicide trials.[8] Women don't want to use oral PrEP because they fear side effects and worry people will assume they are taking antiretroviral medication because they are HIV positive. Tablets are difficult to hide from friends, family or partners.[9]

Microbicide research is increasingly focusing on novel approaches to administration, most notably vaginal rings which could be inserted into the vagina and release anti-HIV medication slowly over a number of weeks. The potential advantage of this type of product over oral PrEP or microbicides is that it doesn't require regular adherence, it can be inserted once a month and is more discrete and possibly cheaper than gels or tablets. Possibly even more promising are long-term injectable antiretrovirals, which are also now in clinical trials.

Commenting on the outcomes of the FACTS 001 trial, Professor Helen Rees, an investigator on the trial, said:

> *'Interviews with participants throughout the study taught us that HIV prevention tools for women must be convenient and take account of complex social and economic realities of their lives. A product that is applied around the time of sex may be suitable for some women, but it did not meet the needs of the majority in our study, most of whom were young, single and lived with their parents. Methods that are easier for women to incorporate into their lives are likely to be more effective.'*[10]

Professor Rees captures well the challenges going forward. There is a pressing need for women-centred HIV prevention methods. But any method must take into account the complex reality of women's lives as well as the enormous barrier presented by HIV stigma.

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# Understanding the promise of biomedical prevention for couples of mixed HIV status: workshop report

By **Christy Newman, Asha Persson, Graham Brown, Jeanne Ellard and Ben Bavinton**

As has been widely discussed, we sit at a historic turning point in scientific understandings of HIV infectiousness with increasing proof now available that antiretroviral treatment can effectively prevent the sexual transmission of HIV. Much of the social research on this development has suggested, however, that people with HIV and those at high risk of acquiring HIV – particularly gay men – remain largely sceptical of the potential of HIV treatment to prevent transmission. Yet the promise of biomedical prevention can hold considerable appeal for those in serodiscordant relationships.

A research workshop hosted at UNSW Australia in May 2015 discussed some of these complexities with reference to emerging results from the first qualitative study of the needs and experiences of couples of mixed HIV status.

Led by the Centre for Social Research in Health (CSRH), YouMe&HIV explores how the emerging HIV 'treatment-revolution' is shaping sexual practices, risk perceptions, service engagement and the everyday realities of living serodiscordantly, among gay and heterosexual couples in metropolitan and regional NSW. The study commenced in 2013, running for three years. During 2013 and 2014, in-depth interviews were conducted with 38 participants in serodiscordant relationships, including 18 HIV-positive and 20 HIV-negative partners.

Given the rapidly evolving nature of this area, the workshop was conducted to provide an opportunity for service providers and stakeholders to be involved at the early stages of research findings rather than at the post-report end, so that the sector input could inform the focus and recommendations of the research report. Workshop participants had policy, practice or research expertise relating to serodiscordant couples.

The workshop was a joint event by CSRH, The Kirby Institute and the Australian Research Centre In Sex, Health And Society (ARCSHS). Facilitator Graham Brown (ARCSHS), provided an overview of the HIV Futures data on serodiscordance across time. This was followed by a presentation from Ben Bavinton (The Kirby Institute) on Opposites Attract, a cohort study of gay men in serodiscordant relationships, and several in-depth and work-in-progress analyses of the YouMe&HIV qualitative data by Asha Persson and Christy Newman (CSRH). Emerging findings were reported in relation to the distinctive

themes of 'pharmaceutical citizenship', 'trust in HIV medicine', 'attitudes to PrEP' and 'making families', providing the basis for lively discussions among the workshop participants.

The promise of biomedical prevention was an overarching theme across the day, starting with Asha's exploration of the way couples with mixed HIV status are making sense of the emerging global strategy of HIV 'treatment as prevention' (TasP). Her presentation posed the timely question: can TasP de-stigmatise serodiscordant sexuality away from its historical moorings in discourses of risk? The potential of treatment to reframe the meaning of serodiscordance was clearly valued by the couples who took part in the study.

As Christy's subsequent presentation noted, study participants also appeared highly trusting of HIV medicine more generally, largely speaking positively about the benefits of treatment and their experiences engaging with care providers. Those who had conceived, or were interested in conceiving children, reported mixed experiences of the understanding and support provided by services. However, this was recognised by study participants to be a rapidly changing field, and one which was also responsible for a 'baby boom' among families affected by HIV in Australia.

Although many study participants were aware of pre-exposure prophylaxis (PrEP), interest varied widely, with half the couples seeing PrEP as irrelevant because they considered serodiscordant sexuality as safe due to TasP, regular testing and, for some, condoms. Others thought that PrEP could play a role in enabling condomless sex and enhance their relationship.

## About the studies

**YouMe&HIV – The Serodiscordant Couples Study**
**http://nchsr.org/youmeandhiv/**

YouMe&HIV aims to produce new empirical knowledge of the needs and experiences of serodiscordant couples in a changing epidemic, with specific focus on how the emerging HIV 'treatment revolution' might shape sexual practices, risk perceptions, service engagement and the everyday realities of living serodiscordantly among gay and heterosexual couples in metropolitan and regional NSW.

The study commenced in 2013 and runs for three years. During 2013 and 2014, in-depth interviews were conducted with 38 participants in serodiscordant relationships, including 18 HIV-positive and 20 HIV-negative partners, representing 24 couples and 1 throuple in total. Data analysis and draft publications are currently in progress.

**Opposites Attract**

Opposites Attract is one of only two clinical studies globally exploring the efficacy of 'treatment as prevention' among homosexual male serodiscordant couples. Along with the primary clinical outcome (transmission of HIV within couples), the study collects detailed data on sexual behaviour, attitudes, relationship agreements, treatments, and understandings of viral load. The study is coordinated by the Kirby Institute and is conducted within 14 clinical sites in Australia, one in Brazil, and one in Thailand. Over 250 couples have been enrolled since early 2012, and over 200 couple-years of follow-up have been accrued. Follow-up is ongoing. The study is currently funded until the end of 2015.

While it is timely to recognise the many benefits of treatment for those who are currently in, or open to exploring, a serodiscordant relationship, a number of issues were also raised and debated during the workshop discussions. Implications for changing understandings of and approaches to disclosure was a concern for a number of workshop participants, as was the recognition that those people who are not able to successfully achieve viral suppression – for varied reasons – are not likely to benefit in the same way. Questions were raised about how services could effectively engage both partners in a serodiscordant couple when most service activities are necessarily focused on (and funded to support) the positive partner. Differences in the needs and experiences of couples identifying as gay or straight were also examined, as were the complex influences of cultural background and geographic location.

A valuable conclusion that emerged from the workshop discussions was that TasP can be incredibly empowering and liberating for couples, enabling a welcome sense of social and sexual belonging and 'legitimacy'. We also need to stay vigilant that TasP does not become a one-size fits-all solution, or a blanket norm that can place coercive obligation on couples and people with HIV more broadly, creating new forms of exclusion and stigma, as well as overshadowing issues such as mental health, immigration, and other social complexities around HIV.

The opportunity to discuss the emerging findings of the study with colleagues in the sector provided insights that will help us ensure the final results are directly pertinent and useful as we navigate the new opportunities and challenges of TasP across communities.

We also need to stay vigilant that TasP does not become a one-size fits-all solution, or a blanket norm that can place coercive obligation on couples and people with HIV more broadly, creating new forms of exclusion and stigma, as well as overshadowing issues such as mental health, immigration, and other social complexities around HIV.

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# Is PrEP a realistic and ethical intervention for people who inject drugs?

By **Chris Gough**

*'[PrEP] is a very expensive way to reduce the risk of HIV transmission, when we know that NSP (needle syringe programs) and handing out harm reduction supplies is such an effective way to reduce HIV, and a lot cheaper. I would rather see a focus on the 15 million people who can't get access to ARV's, rather than trying to get injecting drug users on PrEP.'*

— WHO survey, 2014[1]

Several recent papers have examined whether pre-exposure prophylaxis (PrEP) is a realistic and ethical intervention to address the transmission of HIV in people who inject drugs (PWID). The World Health Organization (WHO), as well as the peer-based International Network of People Who Use Drugs (INPUD) have investigated the attitudes of people in the drug using community, as well as experts in the field.[2,3] This article outlines those findings and discusses their implications for people who inject drugs, both in Australian and internationally.

PrEP is the use of antiretroviral treatment (ART) by HIV-negative people to reduce the risk of acquiring HIV. Several populations of people at risk of HIV exposure have been identified as prime candidates for PrEP: gay men and other men who have sex with men (MSM), serodiscordant couples, young women, sex workers, and people who inject drugs.[4]

While demand for PrEP is growing amongst the gay community, groups representing sex workers and people who inject drugs have conducted surveys which have identified reservations about the use of PrEP in their communities.[5,6] Surveys carried out by the WHO among PWID and health experts reflect similar concerns.[7] Atop the concerns for people who inject drugs is the lack of evidence for PrEP's efficacy in PWID communities. To date, there has only been one study on PrEP use among the drug using community, and its results are widely regarded as flawed.[8]

## Public health and the individual

Before investigating the nuances of PrEP and PWID, it is important to clarify the distinction between public health strategies targeting PWID as a population and the diverse health needs of the individuals which make up this population.

The inclusion of PWID as a key population for PrEP would pave the way for new public health strategies focusing on PWID, such as the funding of PrEP initiatives and legislation targeting PWID. This would have major consequences for PWID communities and individuals (both HIV-negative and HIV-positive); therefore, the inclusion of the PWID population as being 'key' must be considered thoroughly and seriously.

At the level of the individual, it must be recognised that the members of the PWID community are diverse and have different opinions and prerequisites for a healthy life. PWID cut across all walks of life; injecting drug users may be a member of a serodiscordant couple, a sex worker, a gay or bisexual man, or may simply wish to access PrEP to help protect their health. These individuals should all have the option to access any prevention option proven to be safe and effective, cheaply and easily.

## Concerns around population level PWID PrEP programs

The WHO and peer groups such as INPUD have concerns about a public health roll-out of PrEP and its effects on the PWID community, particularly given the criminalised nature of drug use and the systemic problem of stigma and discrimination.[9,10]

The first issue that must be raised concerns mandatory versus voluntary PrEP treatment. Mandatory use of PrEP would cause massive human rights violations and may appear attractive to countries controlled by repressive regimes, with no stomach for harm reduction services. In such countries, PWID are often seen simply as vectors of disease and have no access to targeted health services such as needle and syringe programs or pharmacotherapy.

*'There is a concern that in some countries this will be used to identify possible "vectors" of transmission, especially among key populations and to force them into treatment to prevent transmission to others.'*

— WHO survey, 2014[11]

INPUD's recent PrEP background paper highlights these risks. It cites an example where, in 2013, Gennady Onishchenko (the Chief Sanitary Inspector of the Russian Federation) noted that PrEP could serve as an alternative to methadone opiate substitution, the provision of which is opposed by the Russian government.[12]

*'In the EECA region [eastern Europe and central Asia], people are deeply alarmed by the possibility of their governments picking up on PrEP.*

*[It] raises a whole series of human rights threats and risks: registries that could be shared with the police, compulsory attendance, a whole range of potential human rights infringements . . . '*

— WHO survey, 2014[13]

There is also concern that PrEP may be used in some countries to sideline proven harm reduction services such as NSP and pharmacotherapy.

*'The introduction and backing of PrEP is part of a much larger agenda to medicalize the HIV response, which poses a very serious threat to community-based preventative responses–across all communities. In the context of PWID, the bio-medical magic bullet promised of PrEP, [especially for] governments who are resistant to harm reduction, will be seen as an excuse not to scale up or introduce [proven] harm reduction programming.'*[14]

## Concerns around lack of scientific evidence

There is little doubt that in a clinical setting PrEP reduces the transmission of HIV, however, among people who inject drugs, this efficacy may not translate to the real world. There has only been one study on PrEP as a means of reducing HIV infection in PWID conducted in a real life situation. The Bangkok Tenofovir Study was conducted in 17 Bangkok drug treatment centres, with 2,413 participants over five years. The study was a randomised, double-blind, placebo controlled phase 3 study. The results showed a 48.9% reduction in HIV transmission in the PrEP versus placebo group.[15]

Serious ethical questions have been raised about this study[16]; arguably, it breaches several of the ethical standards outlined in the Council for International Organizations of Medical Sciences (CIOMS) and WHO ethical standards for biomedical research on human subjects[17].

First and foremost, the study failed its ethical obligation to compare the efficacy of PrEP with NSP, the recognised gold standard in HIV interventions for PWID.[18] This occurred because Thailand's narcotics law forbids the distribution of needles and syringes for injecting drug use.

Although clinics in the trial did supply participants with condoms and harm reduction information, as well as bleach for the cleaning of used syringes, no sterile injecting equipment was made available.[19] The trial's inability to negotiate the dispensing of sterile equipment onsite is disappointing because fewer trial participants may have contracted HIV if this had been provided. It also means that PrEP's utility as a complementary intervention to NSP services cannot be gauged.

Other concerns are that study participants were paid; that direct daily observation was used; and that participants who were incarcerated were still allowed access to the PrEP medication.[20] It therefore remains to be seen how well PWID could adhere to a PrEP regimen without incentive, in conditions where daily observation is not possible, and where incarceration (which is common in such a criminalised population) usually means lack of access to medications.

There is no literature available which discusses the logistics of rolling out PrEP to the drug using community. Due to the highly criminalised and stigmatised nature of drug use, people who use drugs often shy away from health services and hide their drug use for fear of negative consequences. Given this fact, it could be difficult to roll out a public health campaign targeting people who use injecting drugs without the support of the PWID community.

## The Australian context

The Australian Injecting and Illicit Drug User League (AIVL) is the peak peer based drug user organisation (DUO) in Australia. AIVL's membership is made up of the state peer-based drug user organisations, whose membership comprises of people who use injecting drugs. It is through this network that PWID are given a voice to share their opinions around topics including PrEP. AIVL is part of INPUD and has adopted the same position on PrEP that is outlined in the INPUD background paper[21].

Looking at Australia, AIVL supports the listing of Truvada for use as a pre-exposure prophylaxis and its inclusion on the Pharmaceutical Benefits Scheme. What is problematic is the listing of people who use injecting drugs as a priority population for PrEP use. The reason for this lies in the practical realities that Australian injecting drug users face.

The rate of HIV among PWID in Australia is between 1–2%[22] whereas hepatitis C (HCV) prevalence is between 50–60%[23,24]. As PrEP does not protect against HCV, NSPs are the pivotal intervention for injecting drug users as they protect against all blood borne viruses.

Currently, Australia's NSP system is struggling to deliver the necessary service coverage to injecting drug users due to inadequate funding and legal and policy barriers. The Australian harm minimisation policy also includes provision of pharmacotherapy programs (methadone, buprenorphine and suboxone treatment). Recent studies show that pharmacotherapy programs can reduce HIV transmission in participants by 54%[25] as well as allowing PWID to stabilise their health and wellbeing in the long term. These realities mean that DUOs must prioritise and constantly push to increase proven harm minimisation service funding in particular NSP, pharmacotherapy, medically supervised injecting facilities, peer education and community development projects.

## Conclusions

The WHO currently does not suggest that PrEP is an effective intervention for PWID due to lack of scientific evidence and survey responses from members of the affected community. Consensus from the drug using community is that making PrEP a priority for PWID is unnecessary and problematic.

DUOs, experts and service providers suggest that PWID are not an appropriate key population for PrEP use. Instead, experts suggest the scaling-up of NSP and pharmacotherapy programs as well as antiretroviral treatment access for HIV-positive PWID is the priority.

Rejection of PrEP as a population health strategy for PWID does not amount to a rejection of an individual's right to access PrEP, or the inclusion of gay men and other men who have sex with men as key populations. PrEP is rejected as a prevention strategy for PWID because the most serious barriers to health in PWID remain NSP inaccessibility, criminalisation and stigma and discrimination.

More details of PWID's views on PrEP will become available when INPUD releases its full position statement later this year.

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# Get PEP

By **Ben Wilcock**

Post-exposure prophylaxis (PEP) is a month-long course of HIV treatments taken within 72 hours of suspected HIV exposure (the sooner the better) to prevent seroconversion.

PEP works because it can take a few days for HIV to become established in the body following exposure to the virus. PEP drugs are administered within the first 72 hours of suspected HIV exposure in an attempt to support the body's immune system to stop the virus from replicating (multiplying). The cells originally infected with HIV die naturally within a short period of time without producing more copies of the virus.

PEP can be an effective HIV prevention tool after a high-risk event, such as condomless sex, sex where a condom breaks, and sharing injecting equipment. For this tool to be effective, those at risk first need to be aware of how PEP works, its availability and where they can access it.

Data from the Gay Community Periodic Surveys shows that there is a significant knowledge gap among gay men regarding the availability of PEP.[1] Knowledge levels vary considerably across the country, ranging from less than half to almost two-thirds of gay men surveyed knowing about PEP and where to obtain it (see Table 1 and Figure 1 on page 49). Among the survey sample, knowledge about PEP is also lower among non-HIV-positive men (which includes HIV-negative men, and men of unknown and untested HIV status) than among all men (see Table 2 and Figure 2).[2–7]

The Seroconversion Study, which focuses on the experiences of people recently diagnosed with HIV, also found a significant knowledge gap regarding the awareness of PEP among gay and bisexual men. Half of the survey respondents who had recently seroconverted were not aware of PEP.[8]

In more recent years, the Gay Community Periodic Surveys have also been asking survey participants about PEP usage in the six months prior to the survey. These results vary across the country, ranging from just over one percent to approximately three-and-a-half percent saying they have accessed PEP in a six-month period (see Table 3).[9–14]

These levels of PEP use highlight a gap between individuals who would be eligible for PEP (based on behaviour) and those that take it.

The Seroconversion Study found a number of reasons for people choosing not to access PEP following a high-risk event. For the men who said they were aware of PEP at the time they seroconverted, reasons included not believing the risk was sufficient enough to have sought PEP. Other reasons related to previous bad experiences when accessing PEP, such as negative attitudes by clinicians or hospital staff. The survey found that these negative experiences can put some people off from accessing PEP after subsequent high-risk events.[15] This reflects other anecdotal reports of people encountering negative attitudes when trying to access PEP.

With varying but relatively low levels of awareness about PEP among gay men around the country, and a gap between those men eligible for PEP and those that take it, the Australian Federation of AIDS Organisations (AFAO) has been developing a national PEP campaign as a way to increase awareness and improve uptake of this important HIV prevention tool. The campaign is currently in the final stages of development.

The primary audience of the campaign will be non-HIV-positive gay men and other men who have sex with men (MSM). However, the campaign is targeted to all gay men and other MSM, including men living with HIV, who are able to inform their non-HIV-positive partners and other men about PEP.

The core information resource for the campaign will be the www.getpep.info website. This is an existing site that will be updated and redesigned as part of the upcoming campaign. The website will contain information about PEP (including what it is, how it works, and tips to follow while taking it), as well as where people can access it.

To help address some of the reasons why some men are not accessing PEP when they would be eligible for its use, the campaign will include information on the reasons or risk events where PEP would be offered, and how to help overcome issues that may be encountered when accessing PEP. Campaign collateral will also include posters, advertisements, and other materials. All other collateral and advertising will direct people to the Get PEP website for more information, including where they can access PEP.

In addition to the campaign, AFAO will also be working and communicating with a broad range of clinical organisations and bodies to increase awareness about PEP and the PEP prescribing guidelines among clinicians throughout Australia.

The development of AFAO's PEP awareness campaign is currently being finalised and is due to be launched in the coming months.

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**Table 3:** Non-HIV-positive men that have used PEP in the six-months prior to the survey (%)

| | 2012 | 2013 | 2014 |
|---|---|---|---|
| **Sydney** | | | 3.6 |
| **Queensland** | | 3.2 | |
| **Perth** | | | 2.3 |
| **Melbourne** | | | 3.3 |
| **Canberra** | | 1.2 | |
| **Adelaide** | 2.4 | | |

**Table 1:** Awareness of PEP availability – all men (%)

| | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 |
|---|---|---|---|---|---|---|
| **Sydney** | | 62.2 | 57 | 58.2 | 60.6 | 63.7 |
| **Queensland** | 53.5 | 53.2 | 50.1 | 55.6 | 64.6 | |
| **Perth** | | 39.9 | | 44.5 | | 47.9 |
| **Melbourne** | | 62.4 | 57.1 | 59.4 | 59.8 | 64.1 |
| **Canberra** | | | | | | |
| **Adelaide** | | 54 | 59.2 | 57.1 | | |

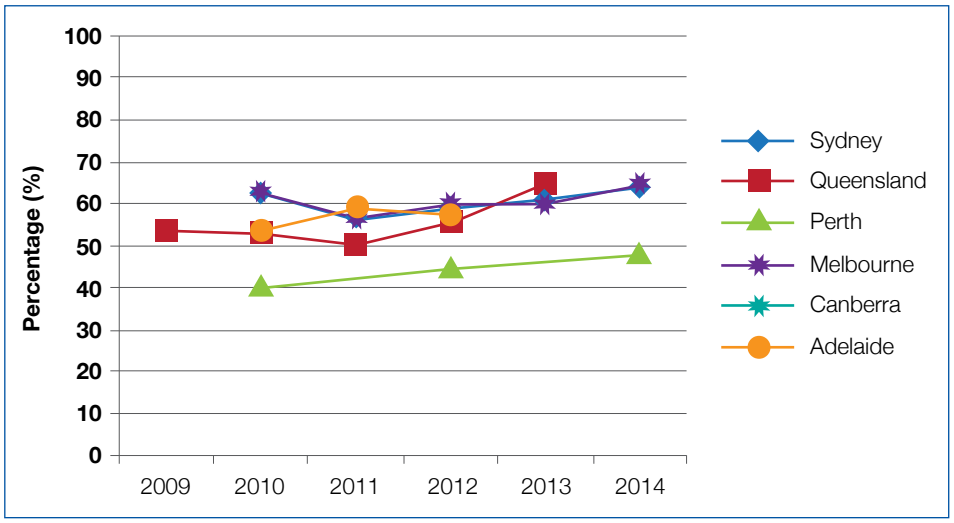


**Figure 1:** Awareness of PEP availability – all men

**Table 2:** Awareness of PEP availability – non-HIV-positive men (%)

| | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 |
|---|---|---|---|---|---|---|
| **Sydney** | | 59.8 | 51.3 | 55.3 | 57.8 | 60.6 |
| **Queensland** | 51.7 | 50.4 | 47.7 | 53.1 | 61.5 | |
| **Perth** | | 38.3 | | 43.3 | | 46.1 |
| **Melbourne** | | 60.3 | 54.6 | 57.4 | 58 | 61.8 |
| **Canberra** | | | 65.4 | | 65.2 | |
| **Adelaide** | | 52 | 58.1 | 56.1 | | |

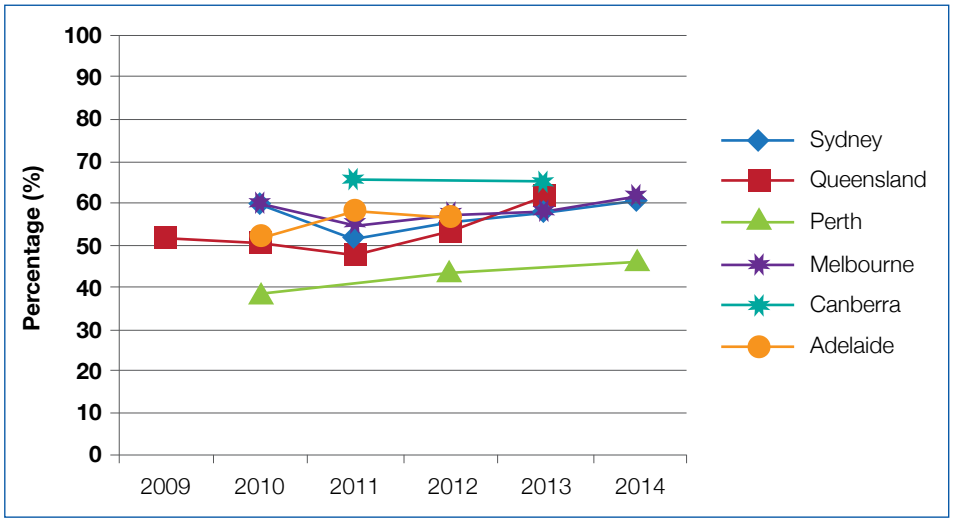


**Figure 2:** Awareness of PEP availability – non-HIV-positive men

# PrEParing Asia and the Pacific: APCOM regional consultations on PrEP

By **Ben Bradstreet, Midnight Poonkasetwatana and Matthew Vaughan**

Globally, the HIV epidemic amongst men who have sex with men (MSM) has expanded, especially in urban settings. Men who have sex with men (MSM) account for more than 33% of new infections in China, and projections indicate that MSM could make up half or more of all new infections in Asia by 2020.[1] HIV prevalence in large mega-cities such as Bangkok, Hanoi and Jakarta ranges from 15% to 25%, which includes a significant cohort of young MSM.[2] Yet these men continue to be excluded from HIV prevention, treatment and care services because of stigma, discrimination and criminalisation. The global HIV pandemic will not be controlled without addressing this situation.

On both public health and human rights grounds, expansion of HIV prevention, treatment, and care to men who have sex with men is an urgent imperative. Effective combination prevention and treatment approaches are feasible, and culturally competent care can be developed – even in rights-challenged environments – but only with a substantial scaling-up of investment in the HIV response and meaningful involvement of the most affected communities.

Condoms and lubricant remain the most cost beneficial and effective HIV intervention, however, despite significant efforts across the region, uptake remains well below the 80% level required to curb new infection rates.[3] It is crucial that HIV prevention efforts respond to the contexts and realities of men who have sex with men's lives through a comprehensive range of effective, accessible and acceptable HIV prevention and harm reduction methods, including biomedical options such as pre-exposure prophylaxis (PrEP).

The WHO *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations*, launched at the AIDS 2014 conference in Melbourne, recommended that: 'Among MSM, PrEP is best offered as one component of a comprehensive set of HIV prevention interventions. Comprehensive HIV prevention programmes should include unfettered availability of condoms and lubricants, routine HIV testing, risk-reduction counselling and adherence coaching if PrEP is offered.'[4]

PrEP presents an important game-changing intervention that can complement existing prevention tools. Furthermore, PrEP is more feasible in concentrated epidemics (such as amongst men who have sex with men in Asia and the Pacific), because community education/mobilisation, resources for HIV testing and antiretroviral therapy (ART), along with interventions to maximise PrEP adherence, can be focused on smaller and confined populations, especially when applied to city-based efforts.[5] On the other hand there are significant operational challenges that need to be considered and overcome, such as community knowledge, the need for frequent testing, monitoring and support. Delivering PrEP implementation requires the scale up of country HIV prevention and care frameworks.[6] These challenges can also be seen as an opportunity to revitalise existing prevention efforts in order to make services and communities 'PrEP-ared'. While we know PrEP will not be a suitable option for all men who have sex with men all of the time, those not taking PrEP can still benefit from reinvigorated health promotion efforts including peer outreach/support, condom/lubricant provision, service referral, testing, treatment and counselling.

## Asia Pacific Coalition on Male Sexual Health (APCOM) leadership, advocacy and community involvement

APCOM is leading the regional consultations on delivering PrEP to men who have sex with men. APCOM advocates nationally, regionally and globally for increased investment in HIV and AIDS responses, in line with the need to scale up and increase coverage of quality, MSM and gay community-led HIV programs and services; research to address gaps in knowledge; and the promotion of individual rights for MSM and transgender people across Asia and the Pacific. As part of this core work, APCOM has made the WHO *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations* accessible to community-based organisations and the populations they serve, by providing easy-to-understand summaries that are relevant to MSM, transgender people and young people.[7]

For any intervention to be effective, it is essential that MSM communities are knowledgeable and empowered to engage in debates about the broad range of issues on the continuum of prevention to treatment, as relevant to provision of HIV and sexual health services. However, there is a lack of knowledge in the region about the science supporting PrEP and the WHO recommendations, and efforts to share this knowledge and engage communities in dialogue on these issues must be sustained. APCOM is dedicated to facilitating community involvement by developing a regional community and stakeholder consultation, to be held in Bangkok later this year, exploring enablers, barriers and issues to inform future PrEP roll-out in the region.

APCOM also proposes to lead some preliminary investigation and an analysis of acceptability of PrEP for HIV prevention among men who have sex with men in Asia and their service providers. Developing a short questionnaire, similar to that used by MSMGF for the survey on 'values and preference of MSM and their service providers' at the global level, APCOM will produce an online survey, with potential scope to also interview a few key informants from the community and national programs. The goal of the survey is to better understand the overall national context, potential entry points, and challenges prior to the regional dialogue.

Existing research has found that the majority of MSM in Thailand, India and China would be willing, or very willing, to use PrEP to complement existing HIV prevention strategies.[8] Furthermore, the possibility of minor side effects and personal cost were not significant deterrents for many people.[9] It is also encouraging that motivation to use PrEP, and adherence to PrEP in clinical trials, is positively correlated to risk, meaning that PrEP is an acceptable prevention method for the men that the MSM pilot programmes would hope to target.[10]

These future surveys will contribute by ascertaining knowledge, attitudes and needs of MSM in other countries in Asia and the Pacific. Moreover, the evidence from iPrEX OLE that PrEP can be considered **at least** 86% effective in preventing HIV infections if taken four to seven times a week (based on no infections over 72 weeks in those adhering to PrEP four or more times a week) can be included in the survey information.[11]

PROUD study interim findings also reported an 86% reduction in HIV transmission, and these findings suggest that PrEP can be successfully applied to real-world setting prevention strategies and services, when MSM are fully informed, engaged and have access to integrated sexual health services.[12] This updated information on PrEP efficacy will hopefully translate into increased acceptability and confidence in PrEP as an additional prevention method among gay and other MSM. The challenge that remains is how to apply the example of PROUD in England, to the Asia-Pacific context?

In the clinical trials for PrEP, one of the biggest challenges has been adherence, so canvassing current and potential PrEP users' preferences, knowledge and needs can help inform how to make pilot programs accessible and acceptable to men who have sex with men. For example, interviews have shown that MSM would prefer to obtain PrEP from a public health clinic, or MSM community-based organisation.[13]

Additionally, iPrEX OLE clinical trial results and the PROUD study indicate that knowledge and information about PrEP's efficacy is crucial to increasing adherence, especially amongst younger MSM.[14] This is important, as young MSM have consistently shown the lowest levels of adherence in clinical trials (those over 40 years of age were three times more likely to have detectable ART levels than those under 25 years in iPrEX OLE[15]). Therefore, consideration of young MSM needs in PrEP pilot programs in the region should be a priority.

## Country Focus of Regional Consultation

APCOM will bring in diverse community voices through an open application process to target countries and territories in Asia, giving priority to those with high prevalence of HIV among gay men, and other MSM.

As the first community-led regional dialogue of its kind, day one will be devoted to community representative discussions on PrEP – building understanding and positions for the region and maximising community involvement and leadership. The following one-and-a-half days will enable a joint dialogue on PrEP between community representatives, national AIDS managers and services providers on viability and feasibility. It is envisaged that discussions and recommendations will aid national decision/policy makers, programmers, development partners, and community members to consider the potential application of PrEP as an additional prevention tool in reducing HIV incidence among high-risk MSM populations.

Following the regional dialogue, a series of national level roll-out dialogues will be planned in select countries with high prevalence and incidence of HIV among MSM, which will inform the development of PrEP demonstration projects.

## Outcomes

Expected outcomes from the PrEP regional consultation include a regional report, which will outline: a set of feasibility and applicability criteria for implementing PrEP in high prevalence settings of the region, a proposed roadmap for national-level PrEP consultation discussions, and a set of regional recommendations/position on PrEP applicability and viability. APCOM will also use the consultation process to create a policy brief or discussion paper on PrEP. However, the broader goal of the consultation process is the expedition of PrEP delivery pilot programs to MSM in urban hotspots, which take on the community needs identified in the consultation, thereby maximising acceptability, accessibility and efficacy.

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husband's family. If you are a sex worker and you speak out about your work, your HIV status, or your rights, you may be risking your life.

I am on the CCM (Country Coordinating Mechanism[1]). When I invited the sex worker group, Friends Frangipani, to join the meeting to develop our concept note, they refused, fearing that they would experience disrespect.

And they are right. Even though I always raise the issues of women and girls and the barriers to sexual and reproductive health, I am not heard, and these programs do not find their way into concept notes.

And let us not forget about the human rights of children and adolescents, especially from key populations. They do not get tested because the age of consent policies force them to disclose their status to their families, risking discrimination.

**Zack:** We want a Global Fund that places health and lives ahead of profits.

From the early days of the HIV response around the world, activists encouraged governments to use TRIPS flexibilities to make quality, generic HIV treatment affordable. The Global Fund was a strong partner in those efforts.

In the MENA region we are continuing that tradition of fighting for hepatitis C treatment.

We realised that the drug user community did not know about coinfections between HIV and hepatitis C. So we used the Global Fund and other donor money to educate them about their right to hepatitis C treatment. We taught them to understand how treatment works and the importance of adherence. We call this treatment literacy.

We learned that the pharmaceutical company, Gilead, was applying for a patent for a hepatitis C in Egypt. The patent would make it impossible for people to afford this drug. So we supported our community to directly approach Egypt's ministry of health to encourage them to resist the patent. This made Gilead nervous and the Egyptian government was able to negotiate a 99% reduction in price for the drug.

We cannot have resilient and sustainable systems for health if the costs of essential medicines are too high. And we cannot have resilient and sustainable systems for health if communities are not funded to do critical advocacy work to make treatment affordable.

**Maura:** That is why we want a Global Fund that supports the contributions of civil society and communities in the fight against the three diseases. We will never accelerate progress to end the three diseases without communities at the centre.

Because of lack of funding for communities in Papua New Guinea, we are still trying to convince our communities to get screened for TB and tested for HIV.

We are still far away from scaling up case-finding for TB or achieving suppressed viral load. Support for scale up of the community-response will make all of the other strategic goals sustainable. That needs to be front and centre in the strategy.

**Zack:** Asia-Pacific has the highest number of new TB cases in the world. It has second largest population of people living with HIV after sub-Saharan Africa. It carries the second largest burden of Malaria in the world.

In the Middle East and North Africa between 2001 and 2012 the number of new HIV infections grew by 52 percent – the most rapid increase in HIV among world regions.

The crisis of the three diseases continues in both of our regions. We must all work together, communities, donors, Board members, Secretariat to deliver the kind of Global Fund that will give the world a chance to finally end AIDS, TB and Malaria in our lifetimes.

Thank you.

## Reference

1 Country Coordinating Mechanisms are central to the Global Fund's commitment to local ownership and participatory decision-making. These country-level multi-stakeholder partnerships develop and submit grant proposals to the Global Fund based on priority needs at the national level.

**Maura Elaripe Mea is from Igat Hope, the national network of HIV-positive people in Papua New Guinea. She is the first HIV-positive woman to come forward publicly about living with HIV in PNG. Zakaria Bahtout is Communications Officer at ITPC-MENA.**

# *Through Our Eyes: Thirty years of people living with HIV responding to the HIV and AIDS epidemics in Australia*

**Edited by** Dr John Rule. **Published by** National Association of People Living With HIV Australia (NAPWHA).

Reviewed by **Michael Frommer**

*Through Our Eyes: Thirty years of people living with HIV responding to the HIV and AIDS epidemics in Australia* is an anthology which spans the extensive history of HIV in Australia. The book – edited by academic and long-time NAPWHA associate, John Rule – collects first-person narratives and reflections on HIV/AIDS activism in Australia from the early '80s to today.

This book features a diverse group of contributors, ranging from HIV-positive people, gay men, sex workers, injecting drug users, Aboriginal and Torres Strait Islanders, clinicians, and government bureaucrats (of course, the identities of many contributors overlap). Here, I will focus on a just a few of the many highlights contained within this impressive collection.

The book opens with the voices of those involved from the start, when the 'AIDS crisis' was first unfolding in Australia. David Menadue describes a defining moment for Australia's HIV movement, when a large group of people came out publicly for the first time as HIV-positive during the third national HIV conference in Hobart in 1988. This laid the groundwork for a more assertive public PLHIV voice going forward.

Ross Duffin recollects the early years of AIDS in Australia with palpable urgency and energy. 'I sat there dumbfounded, thinking it was the end of the world as we knew it' (p. 23). He observes the parallel epidemics which accompanied the emergence of HIV, speaking of the 'epidemic of media sensationalism and bad report', and the 'epidemic of highly inappropriate laws' (p. 24). This struck a chord with me, as these remain issues that still persist to this day.

Next we move to the 1990s. Bill O'Loughlin details the crucial role played by gay activists in setting priorities which were to underpin the policy framework for the AIDS response – both for the gay community and the wider Australian community. He movingly expresses the wicked conundrum that 'In the act of loving another man, I could have killed him' (p. 43).

Paul van Reyk describes the coming together of activists from the gay, sex work and drug using communities – a collaboration which first began with advocacy efforts to reform laws criminalising homosexuality and sex work during the 1970s. He also identifies less well known organisational alliances, such as those between ACON and ACT UP, who tag-teamed as 'good cop, bad cop' in seeking to get speedier access to treatments under Australia's then glacial approval timelines.

Michael Hurley describes the pivotal moment in the mid-90s when highly active antiretroviral therapy (HAART) was first announced during the 1996 Vancouver AIDS Conference. This represented a 'return to living', with a focus on treatment adherence, lipodystrophy and resumption of work.

Our late colleague Alan Brotherton conveys the mixed responses among people with HIV to the new HIV treatments – some people with unbridled enthusiasm, others with scepticism, or even fear – given that a history of negative experiences with drugs that had promised much, but proved to be no silver bullet.

Former NAPWHA Executive Director, Jo Watson, discusses innovative advocacy efforts undertaken by NAPWHA, including supporting HIV-positive people to become key spokespeople (later known as 'treatment advocates'), and the treatment roadshows which toured urban and rural centres.

Katherine Leane provides a moving account about joining the PLWHA (SA) Positive Speakers Bureau. She describes it as a place where she was able to be accepted for the first as time as a woman and mother living with HIV, and a person who injected drugs.

Cameron Cox from Scarlet Alliance, Australian Sex Worker Assocation, highlights the challenges inherent in a criminalised environment, which HIV-positive sex workers experience to this day. He says that while there have been welcome improvements regarding stigma faced by HIV-positive people as a whole, HIV-positive sex workers still feel like they're at the beginning of the epidemic.

John Rule reflects on the role of candlelight memorials as a type of ritual of remembrance, similar to collective funeral rites. 'When we attend an AIDS candlelight rally, we are commemorating that past, those lost lives and lost opportunities. We are mourning, memorialising and remembering, and this is good work we are doing … This memorialising is, I think, sustaining of future for others' (p. 160).

Many narratives in the anthology emphasise the key role that NAPWHA and its member organisations have played over the years, alongside other key events fleshed out through the broad diversity of individuals who were asked to contribute to this collection.

It would have been interesting to also read the perspectives of activists such as Don Baxter, harm reduction advocate Alex Wodak, and organisations representing the other affected communities such as Australian Injecting & Illicit Drug Users League (AIVL) and the Anwernekenhe HIV Alliance (although a contribution from PATSIN highlights clearly some of the issues faced by HIV-positive Aboriginal and Torres Strait Islander people). That said, an anthology of this nature could never be expected to cover everything.

What is particularly valuable are the eye-witness accounts about how things evolved and changed. This collection is a timely reminder that Australia owes a huge debt to the work and legacy of early HIV activists, many of whom are no longer with us. This, in particular, makes the book a very important read.

**Michael Frommer is Policy Analyst at the Australian Federation of AIDS Organisations (AFAO).**

## START TRIAL FINDS THAT EARLY TREATMENT IMPROVES OUTCOMES FOR PEOPLE WITH HIV

**By Gus Cairns**

A major international randomised clinical trial has found that people living with HIV have a considerably lower risk of developing AIDS or other serious illnesses if they start taking antiretroviral treatment (ART) sooner, when their CD4 cell count is above 500 cells/mm$^3$, instead of waiting until their CD4 cell count drops below 350 cells/mm$^3$. These results are likely to have a major impact on international treatment guidelines. The US National Institutes of Health comment in their press release: 'Together with data from previous studies showing that antiretroviral treatment reduced the risk of HIV transmission to uninfected sexual partners, these findings support offering treatment to everyone with HIV.'[1]

The Strategic Timing of AntiRetroviral Treatment (START) study, was a large-scale randomised clinical trial that tested whether earlier ART benefitted all people with HIV. Its predecessor, the SMART study, had a massive impact when it showed, in 2006, that staying on ART was better than interrupting it. Like the previous study, START has been stopped early. Although it was expected to end in December 2016, an interim review of the study data by the study's Independent Data and Safety Monitoring Board (DSMB) recommended that results be released early.

START, which opened widely in March 2011, was conducted by the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT) at 215 sites in 35 countries. The trial enrolled 4685 men and women with HIV who had never taken ART. They were aged 18 and older, with a median age of 36, and their CD4 counts were all over 500 cells/mm$^3$. Half of the study participants were randomised to start ART immediately and the other half deferred treatment until their CD4 cell count declined to 350 cells/mm$^3$. On average, participants in the study were followed for three years.

The study measured a combination of outcomes that included serious AIDS events (such as AIDS-related cancer), serious non-AIDS events (major cardiovascular, renal and liver disease and cancer), and death.

Based on data up to March 2015, the DSMB found 41 instances of AIDS, serious non-AIDS events or death among those enrolled in the group starting ART early, compared to 86 events in those deferring it. This equates to a reduction of 53% in the risk of developing serious illness or death. Concerning AIDS-defining illnesses in particular, the risk reduction was even more pronounced at 70%.

The most common AIDS-related illnesses among study participants were pulmonary tuberculosis, Kaposi's sarcoma, and non-Hodgkins lymphoma. The most common serious non-AIDS-related illnesses were cancer, heart attack, and deaths due to various causes.

Findings were consistent across sites and the benefits of early ART were similar for people from low-, middle- and high-income countries.

More detailed findings are likely to be reported at the International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention in Vancouver in July.

**Adapted from aidsmap.com**
**Published: 27 May 2015.**

### Reference

1 National Institute of Allergy and Infectious Diseases (NIAID). (2015, 27 May). *Starting Antiretroviral Treatment Early Improves Outcomes for HIV-Infected Individuals NIH-Funded Trial Results Likely Will Impact Global Treatment Guidelines.* NIAID media release. US Department of Health and Human Services, Washington, DC. Retrieved from: http://www.niaid.nih.gov/news/newsreleases/2015/Pages/START.aspx

## MODERN NNRTI REGIMENS CAN BE EFFECTIVE WITH 85% ADHERENCE

**By Michael Carter**

Some modern HIV treatment regimens can achieve viral suppression with adherence rates as low as 85%, investigators from the US Veteran Aging Cohort Study report in the online edition of the *Journal of Acquired Immune Deficiency Syndromes*.[1] The authors monitored trends in adherence and viral suppression between 2001 and 2010. Both adherence and rates of viral suppression improved over the course of the study. Moreover, significant increases in rates of viral suppression were observed among people with less than perfect adherence, especially when individuals were taking therapy based on a non-nucleoside reverse transcriptase inhibitor (NNRTI).

Research involving people taking older anti-HIV combinations suggested that it was necessary to take at least 95% of doses at the right time and in the right way to have the best chances of achieving an undetectable viral load. But it's unclear if modern combinations require such a high level of adherence.

To answer this question, investigators monitored rates of adherence and viral suppression among 22,000 HIV-positive veterans over a ten-year period. The authors especially wanted to see if the level of adherence needed to achieve an undetectable viral load differed between regimens based on NNRTIs, protease inhibitors and newer agents such as integrase inhibitors.

People taking NNRTI-based regimens were more likely to have near-perfect adherence than individuals taking combinations containing a protease inhibitor. Users of single-pill therapy had better adherence than people taking multi-pill regimens.

Comparison of patients according to regimen type showed that, at all adherence levels, rates of viral suppression were higher among individuals on NNRTI therapy.

However, for people taking NNRTI-based therapy, an adherence level of 85% was associated with just as high a chance of achieving an undetectable viral load as an adherence rate of 95% or above.

**Adapted from aidsmap.com**
**Published: 12 May 2015.**

### Reference

1 Viswanathan, S., Justice, A., Alexander, G., Brown, T., Gandhi, N., McNicholl, I., et al. (2015). Adherence and HIV RNA suppression in current era of highly active antiretroviral therapy (HAART). *J Acquired Immune Defic Syndr.* doi: http://dx.doi.org/10/1097/QAI.0000000000000643

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# Diary

### July

17–18
**The 7th International Workshop on HIV Pediatrics**
Vancouver, Canada
http://www.virology-education.com

19–22
**8th IAS Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2015)**
Vancouver, Canada
http://www.ias2015.org

### August

13–15
**9th National LGBTI Health Conference (Health in Difference 2015)**
Canberra, Australia
http://healthindifference.org

### September

13–16
**World STI and HIV Congress**
Brisbane, Australia
http://www.worldsti2015.com

16–18
**Australasian HIV&AIDS Conference**
Brisbane, Australia
http://www.hivaidsconference.com.au

### October

5–6
**6th HIV & Aging Workshop 2015**
Washington, DC, United States of America
http://www.virology-education.com

### October

18–21
**24th International Harm Reduction Conference 2015**
Kuala Lumpur, Malaysia
http://www.ihra.net/conference-2015

### November

20–23
**12th International Congress on AIDS in Asia and the Pacific (ICAAP12)**
Dhaka, Bangladesh
http://www.icaap2015.org

22–27
**International Conference on AIDS and STIs in Africa (ICASA) 2015**
Tunis, Tunisia
http://icasa2015tunisia.org

### December

8–11
**7th International Workshop on HIV Persistence, Reservoirs and Cure**
Miami, United States of America
http://www.hiv-persistence.com

16–18
**The 2nd International Conference on HIV/AIDS, Women and Children**
Shiraz, Iran
http://ichawc2.sums.ac.ir/en/

ENDING HIV

# TREAT TO MAKE HIV UNDETECTABLE

Improve health, reduce transmission.

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