Australian Federation of AIDS Organisations

Comments to the Pharmaceutical Benefits Advisory Committee:

Application by Gilead to list Truvada for use as HIV pre-exposure prophylaxis

Executive Summary

Australia's *Seventh National HIV Strategy 2014-2017* sets the framework and direction for Australia's national response to HIV. [1] The Strategy sets a world-leading **goal of virtually eliminating HIV transmission in Australia by 2020**, and establishes ambitious targets to reduce HIV infection rates and increase the percentage of people with HIV on antiretroviral treatment. Australia has a national, bipartisan commitment to this goal, with all members of the Council of Australian Governments Standing Council on Health endorsing these targets in 2013. There has been excellent progress on increasing treatment rates for people living with HIV, but **no progress on reducing national infection rates**. In 2014 there were 1,081 HIV infections newly diagnosed, with gay and other men who have sex with men accounting for 70 per cent of those diagnoses.[2]

PrEP is potentially the game-changer that will make reaching the 2020 HIV prevention target possible – but only if it is accessible and affordable for those most at risk of HIV. Both the UK PROUD study and the French and Canadian IPERGAY trials reported 86% reductions in risk of HIV infection among participants using PrEP to prevent HIV infection.[3] Conservative analysis by the Kirby Institute for Infection and Immunity in Society[4] indicates that making PrEP available to just those gay men at highest risk of acquiring HIV would reduce HIV diagnoses in Australia by 44 per cent in the first 12 months, preventing 332 people from acquiring HIV.[5]

The TGA's registration of Truvada as PrEP on the Australian Register of Therapeutic Goods is welcome, but **the cost of PrEP remains prohibitive for most Australian gay men and men who have sex with men**.

The cost of providing Truvada as PrEP under the PBS to a person for periods they are likely to be at high-risk of acquiring HIV, is likely to be minimal when compared to the cost of lifetime treatment of that individual if they acquire HIV. The cost of providing PrEP under the PBS to gay men and others most at risk of HIV infection would be more than offset by savings from HIV infections averted – both for individuals taking PrEP, and for their sexual partners.

HIV is a communicable disease, with every infection averted potentially also preventing further onward infections**. PrEP must be recognised as a timely public health intervention** providing not only personal protection from HIV, but also protecting others who might also have acquired HIV had the infection not been averted.

AFAO, AIDS Councils and research organisations running PrEP demonstration projects are already providing **PrEP education resources** that emphasise the importance of daily adherence and recommend strategies to help users remind themselves to take PrEP.[6] It will be straightforward for these communications to continue once PrEP is added to the PBS.

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1 Available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-hiv

2 The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2015. The Kirby Institute, UNSW Australia.

3 For further information and comment on these studies, see:
- CDC Statement on IPERGAY Trial of Pre-Exposure Prophylaxis (PrEP) for HIV Prevention among Men Who Have Sex with Men (CDC media statement)
- Pre-exposure prophylaxis (PrEP) stops 86% of HIV infections in PROUD study (aidsmap.com)
- Pre-exposure prophylaxis also stops 86% of HIV infections in IPERGAY study (aidsmap.com)
- PrEP Proactive Responsible Empowered Pleasure (Living Positive Victoria media release)
- PrEP for gay men, serodiscordant heterosexual couples and women (Sean Slavin, AFAO, for ASHM blog)

4 For more information on the Kirby Institute: https://kirby.unsw.edu.au/about-us

5 Zablotska, I. (Kirby Institute, UNSW) (2015, 18 September). The Australian National PrEP Guidelines and Potential Impact of PrEP on HIV Prevention in Australia. Paper presented at the Australasian HIV and AIDS Conference 2015, Brisbane, 18–22 September.

6 For example, see EPIC-NSW Information for Participants booklet: http://endinghiv.org.au/nsw/wp-content/uploads/2015/02/EPIC-NSW-Information-for-participants.pdf

Neither the PROUD nor the IPERGAY study found evidence of increased sexual risk taking among PrEP users.[7] The PROUD study in particular indicates that **PrEP would be highly effective in a 'real-world' setting** similar to trial contexts with community GPs and health clinics providing access to PrEP, and community HIV agencies providing education and support — the way PrEP would be rolled out if it were subsidised under the PBS.

PrEP will allow for an increase in regular and comprehensive STI testing and treatment. Social research indicates that there is considerable room to improve comprehensive HIV/sexual health testing rates[8] and the frequency of re-testing. Quarterly STI screening of PrEP users has the potential to significantly increase the detection and treatment of STIs, and mitigate potential transmission to sexual partners.

PrEP is registered for use in an increasing number of countries and **is recognised by the World Health Organisation as a key HIV prevention tool**.

PrEP prescribing and dispensing arrangements need to be flexible. There is no clinical basis for placing an s100 restriction on prescribing arrangements for Truvada as PrEP. Should PBAC consider it necessary to limit prescribing however, we recommend that PBAC specify the criteria of interest or relevance, with State and Territory Departments of Health then overseeing the requirements and providing authorisation for prescribers of s100 HIV medications (in this case, Truvada) as PrEP. These criteria would be different to the requirements for prescribing s100 HIV treatments, due to lesser clinical complexity. This arrangement would maximise the potential for equitable and properly targeted access to PrEP.

A fair price for Truvada as PrEP can be negotiated. **The price for Truvada PrEP should be lower than that for Truvada as treatment, given the purpose of its use is different and it is is not a new drug.**

AFAO proposes the following clinical criteria for prescribing Truvada for PrEP through the PBS:

> Truvada for PrEP should be offered to any person who is assessed as being at high risk of acquiring HIV infection, taking into account risk factors arising from condomless anal or vaginal sex or injecting drug use.

There is strong recognition internationally that PrEP is effective and that its delivery needs to be integrated into health systems – to "put the strong and consistent evidence of PrEP efficacy into practice."[9] PrEP is a powerful HIV prevention tool, and facilitating its use has the potential to break the cycle of HIV transmission among gay men in Australia. We have the systems and infrastructure in place – not least through our community AIDS Councils and community networks – to integrate PrEP education and health promotion resources into existing education and care arrangements. For Australia, TGA approval of use of Truvada as PrEP is just the first step. Australia has demonstrated that it can show the leadership and foresight required to sustain a world-leading public health approach to HIV prevention. **PrEP needs to be listed on the PBS if we are to meet our commitment to virtually eliminating new HIV transmissions in Australia by 2020.**

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7 Fonner VA, Dalglish SL, Kennedy CE, et al. Effectiveness and safety of oral HIV pre-exposure prophylaxis (PrEP) for all populations: A systematic review and meta-analysis. AIDS May 5 2016 doi: 10.1097/QAD.0000000000001145

8 de Wit J, Mao L, Adam P, Treloar, C. HIV/AIDS, hepatitis and sexually transmissible infections in Australia: Annual report of trends in behaviour 2015. Sydney: Centre for Social Research in Health, UNSW Australia.

9 "Pre-exposure prophylaxis works – it's time to deliver". The Lancet. Vol 385. April 18 2015, p. 1483.

About AFAO

AFAO is the national federation for the HIV community response. AFAO's members are the AIDS Councils in each State and Territory; the National Association of People with HIV Australia; the Australian Injecting and Illicit Drug Users League; the Anwernekenhe National HIV Alliance; and Scarlet Alliance, the Australian Sex Workers Association.

AFAO advocates on behalf of its member organisations, promotes medical and social research into HIV and its effects, develops and formulates policy on HIV issues, and provides HIV policy advice to the Australian Government, including via its membership of the inter-governmental Blood Borne Viruses and Sexually Transmissible Infection Standing Committee.[10]

The *Seventh National HIV Strategy 2014-2017* sets the framework and direction for Australia's national response to HIV, and represents the commitment of governments and civil society to addressing the impact of HIV on the Australian population. [11] The National HIV Strategy provides a framework for action and accountability with objectives to scale up prevention, testing, management, care and support for people living with, and at risk of, HIV at the national level, with action on HIV at local levels aligning with the National HIV Strategy. All jurisdictions acknowledge that undertaking action to achieve these goals requires governments, clinicians, researchers and communities to work together.

The leadership and efforts of communities living with and affected by HIV – represented by AFAO – has been central to Australia's internationally esteemed response to HIV. AFAO and its members have a unique ability to reach and engage with communities. This role complements and supports effective government action and ensures the meaningful involvement of people living with HIV and affected communities in Australia's HIV response. The role of the HIV community sector in implementing the National HIV Strategy includes communicating with affected populations, identifying opportunities for cooperative action, delivering targeted programs and providing information to government on the needs of priority populations. AFAO provides a trusted communication channel between affected communities and the HIV partnership.

In this role, AFAO has a unique contribution to make to discussions regarding access to HIV pre-exposure prophylaxis (PrEP) in Australia. AFAO welcomes the opportunity to provide comment as the PBAC considers Gilead's application for PBS listing of Truvada for use as HIV PrEP.

1. Enhancing access to PrEP is essential if we are to achieve National HIV Strategy goals

The National HIV Strategy sets a world-leading goal of virtually eliminating HIV transmission in Australia by 2020. It establishes ambitious targets to reduce HIV infection rates and increase the percentage of people with HIV on antiretroviral treatment. In 2013, all members of the Council of Australian Governments Standing Council on Health endorsed these targets, which are drawn from

[10] The BBVSS is the principal inter-governmental committee planning, advising on and responding to HIV, comprising representatives from State and Territory Health Departments. The BBVSS reports to the Australian Health Ministers' Advisory Council through the Australian Health Protection Principal Committee on policy, programs and social issues related to HIV, viral hepatitis and STIs.

[11] Available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-hiv

Australia's commitment to the United Nations Political Declaration on HIV,[12] and in 2014, Australia's Health Ministers agreed to the goal of virtually eliminating new HIV infections in Australia by 2020.

There has been excellent progress on increasing treatment rates for people living with HIV, but no progress on reducing national infection rates. Over the three years from 2012 to 2014, the HIV infection rate in Australia remained stable. In 2014 there were 1,081 HIV infections newly diagnosed, with gay and other men who have sex with men accounting for 70 per cent of those diagnoses.[13]

PrEP is potentially the game-changer that will make reaching the 2020 HIV prevention target possible – but only if it is accessible and affordable for those most at risk of HIV. The most direct and effective means of targeting PrEP to those most at risk of HIV is to list Truvada as PrEP on the PBS. Conservative analysis by the Kirby Institute for Infection and Immunity in Society[14] indicates that making PrEP available to just those gay men at highest risk of acquiring HIV would reduce HIV diagnoses in Australia by 44 per cent in the first 12 months, preventing 332 people from acquiring HIV.[15]

This submission focuses on how best to ensure that gay men at risk of HIV are aware of PrEP as a prevention tool, and how to ensure that PBS listing of Truvada PrEP facilitates a reduction in HIV diagnoses by targeting those most at risk.

2. Australia's gay community is ready for PrEP

Gay community organisations and individual activists have been central to leading Australia's community response to HIV for over thirty years, working as part of the HIV sector to develop and promote innovative prevention strategies that respond to advances in scientific knowledge and behavioural research. At the same time, community organisations have identified and sought to address structural barriers that can impede the timely adoption and rollout of new prevention strategies.

Over the past two years, there has been concerted advocacy by the HIV community sector toward enhancing access to PrEP in Australia. This advocacy was energised by the announcement at the 2015 International Conference on Retroviruses and Opportunistic Infections, that both the UK PROUD study and the French and Canadian IPERGAY trials had reported 86% reductions in risk of HIV infection among participants using PrEP to prevent HIV infection. [16]

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[12] Available at: http://www.unaids.org/sites/default/files/sub_landing/files/20110610_UN_A-RES-65-277_en.pdf

[13] The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2015. The Kirby Institute, UNSW Australia.

[14] For more information on the Kirby Institute: https://kirby.unsw.edu.au/about-us

[15] Zablotska, I. (Kirby Institute, UNSW) (2015, 18 September). The Australian National PrEP Guidelines and Potential Impact of PrEP on HIV Prevention in Australia. Paper presented at the Australasian HIV and AIDS Conference 2015, Brisbane, 18–22 September.

[16] For further information and comment on these studies, see:
- CDC Statement on IPERGAY Trial of Pre-Exposure Prophylaxis (PrEP) for HIV Prevention among Men Who Have Sex with Men (CDC media statement)
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- PrEP Proactive Responsible Empowered Pleasure (Living Positive Victoria media release)
- PrEP for gay men, serodiscordant heterosexual couples and women (Sean Slavin, AFAO, for ASHM blog)

These findings indicate that when PrEP is properly targeted to those who are at risk of acquiring HIV, PrEP users will generally continue with whatever risk behaviours and risk reduction strategies they used prior to taking the drug. Neither the PROUD nor the IPERGAY study found evidence of increased sexual risk taking, which allays concerns that PrEP may lead to risk compensation. Furthermore, a meta-analysis of 18 PrEP studies has also found no evidence of risk compensation.[17] The PROUD study in particular confirmed that PrEP is highly effective in a 'real-world' setting, that is, with participants accessing PrEP through health clinics in the community — the way it would be delivered if it were subsidised under the PBS — not only where access is provided under the highly-controlled clinical trial conditions.

3. PrEP is a key component of combination HIV prevention approaches

As recognised in Australia's National HIV Strategy, a mixture of behavioural, biomedical and structural approaches will enable us to drive down HIV infection rates. AFAO and its members have mobilised, engaged and educated gay men regarding the 2020 goal of ending HIV transmission and there have been significant achievements in enhancing community health literacy about the need for frequent HIV testing and immediate treatment.

As part of this comprehensive approach to HIV prevention, PrEP has great potential to drive down HIV infection rates among Australian gay men – if it is affordable for those most at risk. Gay men are already accessing affordable PrEP via online personal importation, but PBAC listing of Truvada would provide access to the drug that has been approved by the TGA, with quality assured. PBS listing is essential if this game-changing prevention tool is to be targeted to and available to those most at risk of HIV.

4. Australian gay men have high levels of health literacy

Throughout the HIV epidemic, gay men have demonstrated high levels of health literacy with knowledge continuing to evolve in response to scientific advances. Awareness of PrEP among gay men in Australia has grown rapidly over the past few years and the findings that PrEP has proven effective at reducing HIV infections, particularly in real world settings, has engaged many in the community. In 2015, the Australian PrEPARE survey reported that three quarters of respondents had heard of PrEP.[18] In 2016, a community survey found that 89 per cent of gay men had heard a lot or a little about PrEP, with two thirds of those who had heard of PrEP aware that it is an effective way of preventing HIV infection.[19] Gay and other homosexually active men who have heard of PrEP generally have a positive response to discussion of PrEP.[18]

Australia's State and Territory AIDS Councils are responding to community interest and have convened many community forums to provide information on PrEP and access options in recent years. There is also considerable community activism and interest with three community groups (PrEPAccessNow[20], PreP'D for Change[21], and Time4PrEP[22]) working to promote and advocate for access, and to support gay men interested in accessing PrEP.

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17 Fonner VA, Dalglish SL, Kennedy CE, et al. Effectiveness and safety of oral HIV pre-exposure prophylaxis (PrEP) for all populations: A systematic review and meta-analysis. AIDS May 5 2016 doi: 10.1097/QAD.0000000000001145

18 Holt M, Lea T, Kippax S, et al. Awareness and knowledge of HIV pre-exposure prophylaxis among Australian gay and bisexual men: results of a national, online survey. *Sexual Health*. 2016. Advance online publication. http://dx.doi.org/10.1071/SH15243

19 Spina A, Test Often Evaluation, ACON, 2016.

20 For more information: http://www.prepaccessnow.com.au

21 For more information: http://prepdforchange.com/home.html

5. Gay men at high risk of HIV are willing to use PrEP

The PrEPARE study, which examined gay and bisexual men's attitudes toward biomedical HIV prevention, has found that 32 per cent of HIV-negative and untested respondents showed a willingness to use PrEP.[23]

Real world considerations in making a decision whether or not to use PrEP include perceived self-risk of HIV infection, the cost of PrEP, prescribing and dispensing options, and willingness to engage in regular clinical monitoring. When these considerations are taken into account, the proportion of HIV-negative men who may come forward to request PrEP is likely to be significantly smaller than the 32 percent of PrEPARE participants willing to use PrEP, given that a research participant's willingness to take PrEP does not necessarily translate to an actual decision to use PrEP. In 2014, with uptake mostly limited to personal importation or small demonstration projects, about three per cent of gay or bisexual HIV-negative men with casual sexual partners had used PrEP in the prior six months.[24]

6. Gay men in Australia are already using PrEP

The two main means by which gay men in Australia currently access PrEP are by importing generic drugs for personal use via online purchase (Personal Importation Scheme), or by enrolling in a PrEP demonstration project.

- Personal importation: several online pharmacy sites offer tenofovir/FTC combination generics for sale. These sites require an Australian-issued doctor's prescription.
- Demonstration projects: interim arrangements are in place for access to PrEP via trials in New South Wales, Victoria and Queensland. Approximately 8,300 places are planned to be available to residents of those states at the time of writing.

There are risks associated with personal importation: the safety and quality of the drugs purchased cannot be guaranteed; and while most sites require a prescription for purchases, there is the potential for drugs to be purchased without a prescription or for a prescription to be reused. There is also potential for patients to access PrEP without regularly seeing a doctor for monitoring and other primary health care.

To facilitate safe use of PrEP, AFAO and its members have posted information on our websites regarding the legality and safety of purchasing PrEP online. These activities constitute a practical effort to inform gay men of PrEP access options and help ensure the risk of harm is minimised.

7. Gay men currently using PrEP in Australia are showing high levels of adherence

While adherence to drug dosage regimens can be challenging, early findings from the PrEP demonstration projects in NSW and Victoria show very high levels of adherence.

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[22] For more information search Facebook: 'Time4PrEP'

[23] de Wit J, Mao L, Adam P, Treloar C. HIV/AIDS, hepatitis and sexually transmissible infections in Australia: Annual report of trends in behaviour 2015. Sydney: Centre for Social Research in Health, UNSW Australia.

[24] de Wit J, Mao L, Adam P, Treloar C. HIV/AIDS, hepatitis and sexually transmissible infections in Australia: Annual report of trends in behaviour 2015. Sydney: Centre for Social Research in Health, UNSW Australia.

The importance of drug adherence is a familiar concept in the gay community. People living with HIV are very aware of the need for drug adherence. HIV-negative gay men, given their contact with people with HIV and overall high levels of HIV health literacy, are also aware that the effective treatment of HIV requires individuals to adhere to the daily dosing regimen. The PrEPARE study found that men who had heard of PrEP tended to know that its efficacy depends on taking the drug as prescribed.[25] Both ViCPREP and PRELUDE have reported therapeutic drug levels in patients on PrEP.

8. Individuals at risk of HIV infection require affordable access to PrEP

The TGA's registration of Truvada as PrEP on the Australian Register of Therapeutic Goods is very welcome, but the cost of PrEP remains prohibitive for most Australian gay men. If Truvada PrEP is not listed on the PBS, most gay men who now use PrEP purchased online will continue to do so, and will continue to be exposed to the risks regarding the quality and safety of imported products, and the potential to be disconnected from primary health care.

From the PrEPARE study we know that gay men who perceive themselves to be at risk of HIV are more likely to be willing to use PrEP, that is, those who engage in condomless sex with casual partners, who have previously taken post-exposure prophylaxis or who have an HIV positive regular partner.[26] The PrEP demonstration projects have found that they are diagnosing HIV infections during enrolment, indicating that at-risk individuals are self-selecting for PrEP.

9. PrEP is likely to be used for periods of time when an individual's risk of HIV infection is higher.

The findings and analyses from the PrEPARE study indicate that it is likely to be a minority of gay men who are interested in taking PrEP. Gay men's sexual practice, as for most adults, varies significantly through life. Gay men who do choose to take PrEP are likely to use it only for periods when their risk of HIV transmission is elevated, that is, for periods of time rather than continuously throughout adult life. There will be in most people's lives periods of sexual inactivity, periods in monogamous relationships, and other periods when a person may be sexually active with casual partners. PrEP is most useful for those individuals who recognise that their risk is elevated at certain points, and who regard PrEP as providing the best available protection against HIV during those periods.

The cost of providing Truvada as PrEP to a person during periods they are likely to be at high-risk of acquiring HIV is likely to be minimal when compared to the cost of lifetime treatment of that individual if they acquire HIV. AFAO is cognisant of the cost-benefit consideration that PBAC is required to make. We are confident that the cost of providing PrEP under the PBS to gay men and others most at risk of HIV infection would be more than offset by savings from HIV infections averted – both for individuals taking PrEP, and for their sexual partners.

We strongly encourage PBAC to recognise the nature of HIV as a communicable disease, with every infection averted potentially also preventing further onward infections. In this way, PrEP must be

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[25] Holt M, Lea T, Kippax S, et al. Awareness and knowledge of HIV pre-exposure prophylaxis among Australian gay and bisexual men: results of a national, online survey. *Sexual Health*. Advance online publication. 2016. http://dx.doi.org/10.1071/SH15243

[26] Holt M, Lea T, Kippax S, et al. Awareness and knowledge of HIV pre-exposure prophylaxis among Australian gay and bisexual men: results of a national, online survey. *Sexual Health*. Advance online publication. 2016. http://dx.doi.org/10.1071/SH15243

considered as a public health intervention providing not only personal protection from HIV, but also protecting others who might also have acquired HIV had the infection not been averted. AFAO urges PBAC to consider the cost-effectiveness of PrEP at both the individual and the population level, since it is at both levels that Australia will benefit from this intervention.

10. Gay men have the health literacy to make informed decisions about the risks associated with PrEP use

Throughout the HIV epidemic gay men have shown high levels of health literacy regarding HIV which have informed individual decisions about prevention strategies. PrEP does present some risks, particularly if the dosing regimen is not adhered to; however, there are inherent risks in the variety of strategies gay men use to prevent HIV infection, including, for example, incorrect or inconsistent use of condoms. This has not discouraged men from assessing HIV risk and making a personal decision that is appropriate for them. The very nature of the HIV risk has required gay men to balance their natural, human wish for intimacy with the potential for acquiring HIV. Gay men have made considered HIV risk calculations for more than thirty years, and will continue doing so, weighing up the benefits that PrEP may offer against the risks it may pose.

While there may be side effects for people using PrEP for protracted periods, it is likely that gay men will use PrEP only during periods of elevated HIV risk. For highly sexually active gay men who need to use PrEP longer-term for HIV prevention, ongoing clinical care and monitoring will help with the management of any side effects.

To ensure the effectiveness of PrEP for individual users and as a prevention strategy to drive down HIV infection rates among gay men, there will need to be significant efforts to promote awareness of the importance of adherence to dosing regimens. Consultations for prescription repeats will present a face-to-face opportunity to reinforce the importance of adherence and for regular STI testing. This will complement community organisations' education and health promotion programs. AFAO, AIDS Councils and research organisations running the demonstration projects are already providing PrEP communication resources that emphasise the importance of daily adherence and recommend strategies to help users remind themselves to take PrEP.[27] It will be straightforward for these communications to continue once PrEP is added to the PBS.

11. The gay community will adapt prevention strategies to incorporate PrEP

Some concern has been expressed about the potential impact of PrEP on sexual behaviour, particularly the impact it may have on rates of condomless anal sex among PrEP users.

Although overall rates of condom use during anal intercourse with casual partners have remained high, gay men have found a variety of ways to reduce the risk of HIV infection if they are not using condoms. These risk reduction strategies include: 'serosorting' (having sex with men of the same HIV sero-status); 'strategic positioning' (for example, the HIV negative partner taking the insertive position during anal intercourse); 'negotiated safety' (condomless sex within relationships); monitoring viral load (with condomless sex when viral load is undetectable); and post-exposure prophylaxis. PrEP will augment these existing risk reduction strategies.

[27] For example, see EPIC-NSW Information for Participants booklet: http://endinghiv.org.au/nsw/wp-content/uploads/2015/02/EPIC-NSW-Information-for-participants.pdf

It needs to be acknowledged that concerns regarding the 'risk' of condomless sex can be moralistic and homophobic, with gay men being told that a desire to use PrEP equates with complacency about HIV. Sex without condoms occurs because it is generally more pleasurable and intimate; gay men are no different in this respect to other sexually active adults. Just as the contraceptive pill enabled women to have condomless sex while being protected against pregnancy, PrEP enables gay men who may not always be using condoms to guard against HIV infection.

Gay men are adapting to PrEP just as they have adapted to other developments. Whatever choices gay men make, it is up to each sexually active gay man and his sexual partners to make decisions about HIV risk and safety. PrEP is alleviating many men's fear of acquiring HIV, a fear that has been present throughout most gay men's sexual lives. As outlined above (section 2), findings from both the UK PROUD study and the French and Canadian IPERGAY trials indicate that when PrEP is properly targeted, users will generally continue with whatever risk behaviours and risk reduction strategies they used prior to taking the drug. Neither the PROUD nor the IPERGAY study found evidence of increased sexual risk taking.[28] The PROUD study in particular indicates that PrEP would be highly effective in a 'real-world' setting similar to trial contexts with community GPs and health clinics providing access to PrEP, and community HIV agencies providing education and support — the way PrEP would be rolled out in Australia if it were subsidised under the PBS.

12. PrEP will allow for an increase in regular and comprehensive STI testing and treatment

Early findings from the PrEP demonstration projects in Victoria and NSW are showing a decline in condom use; this is entirely expectable as PrEP offers sufficient protection from HIV that condoms are not additionally required for protection unless a person's sexual partner indicates a wish to use them. Trial participants were already having condomless sex prior to starting on the trials and although some men's consistent use of condoms may have dropped further while participating in the trial, PrEP provided them with protection from HIV. Additionally, these studies only tell us about the impact of condom use among participants of the study, not the overall impact PrEP may have on condom use within the gay community. The studies highlight the importance of ensuring that PrEP is accessible to those who are already having some condomless sex and whose risk is already elevated.

Testing guidelines recommend that gay men and other men who have sex with men who engage in sexual risk behaviours test for HIV and other STIs up to four times a year.[29] Social research indicates that there is considerable room to improve comprehensive HIV/sexual health testing rates[30] and the frequency of re-testing. Quarterly STI screening of PrEP users has the potential to significantly increase the detection and treatment of STIs, to integrate sexual health monitoring into overall health care and mitigate potential transmission of STIs to sexual partners.

13. PrEP is registered for use in an increasing number of countries and is recognised by WHO as a key HIV prevention tool

PrEP has been registered for use in the USA, France, South Africa, Kenya, Israel, Canada and Peru.

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[28] Fonner VA, Dalglish SL, Kennedy CE, et al. Effectiveness and safety of oral HIV pre-exposure prophylaxis (PrEP) for all populations: A systematic review and meta-analysis. AIDS May 5 2016 doi: 10.1097/QAD.0000000000001145

[29] For more information: http://stipu.nsw.gov.au/wp-content/uploads/STIGMA_Testing_Guidelines_Final_v5.pdf

[30] de Wit J, Mao L, Adam P, Treloar, C. HIV/AIDS, hepatitis and sexually transmissible infections in Australia: Annual report of trends in behaviour 2015. Sydney: Centre for Social Research in Health, UNSW Australia.

France is the first and only country with a centrally organised, reimbursable health system to approve PrEP. The National Health Service England (NHS England) has determined it would not make PrEP available under the NHS because the NHS does not have responsibility for commissioning HIV prevention services[31].

In November 2015, the World Health Organization (WHO) released its Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection, recommending PrEP for all populations at substantial risk of acquiring HIV.[32] The WHO Guidelines recommend that PrEP be used as part of a combination of HIV prevention approaches.

Within the Asia Pacific region, there is increasing action to prepare for PrEP. The Asia Pacific Coalition on Male Sexual Health, with support from UNAIDS and WHO, has developed actions under the *PrEParing Asia* banner, setting out advocacy and delivery strategies, including specific roll-out action plans for six countries.[33]

14. PrEP prescribing and dispensing arrangements need to be flexible

Most gay men access their primary healthcare, including their sexual health care, via their local GP rather than with an authorised s100 prescriber or specialist doctor. If PrEP is to be targeted to people most at risk of acquiring HIV, there must be no unnecessary barriers to obtaining a prescription.

Restricting who can prescribe PrEP, for example to specialists and doctors who are trained and accredited section 100 HIV treatment prescribers under current arrangements, would present a significant barrier for people who cannot access one of these clinicians or a sexual health clinic, including people in rural and regional areas. Some States and Territories have very low numbers of s100 treatment prescribers and they, as well as specialist doctors, are generally clustered in metropolitan areas. This would effectively make access to PrEP unavailable for a gay men at high risk in an area with no s100 treatment prescribers, relevant specialists or sexual health services.

There is no reasonable clinical basis for requiring the same s100 training and accreditation arrangements for prescribing Truvada as PrEP as those that apply for prescribing of HIV treatments. Prescribing Truvada as PrEP is not clinically complex, and decisions about prescribing are well within routine standards of clinical practice for general practitioners. Restricting prescribing to current s100 arrangements in place for HIV treatment drugs, including Truvada, would dislocate patients from their existing care arrangements, increase the fragmentation of care – with sexual health care being sought separately from other primary health care, or result in patients who need access to PrEP being unable to access it. In order for the impact of PrEP to be maximised and for its public health benefits to be realised, prescribing arrangements should facilitate its delivery to people at the highest risk of HIV.

Should PBAC consider it necessary to limit prescribing however, AFAO recommends that PBAC specify the criteria of interest or relevance, with State and Territory Departments of Health then overseeing the requirements and providing authorisation for non-specialist prescribers of s100 HIV prevention medications (in this case, Truvada PrEP). Authorisation would occur based upon s100

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[31] See https://www.england.nhs.uk/2016/05/prep-provision/

[32] Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection what's new. World Health Organization, 2015.

[33] APCOM. PrEParing Asia. Meeting report.

providers satisfactorily meeting requirements such as the completion of short online training on prescribing guidelines and the need for ongoing HIV testing and monitoring of kidney and bone health. This would create two categories of s100 providers for HIV drugs: for treatment - with training and certification reflecting its clinical complexity; and for dispensing of Truvada as PrEP. This arrangement would maximise equitable and properly targeted access to PrEP, and set the scene for ensuring that people outside metropolitan areas of major cities have access to a PrEP prescriber.

PrEP should be dispensed through community pharmacies.

15. A fair price for Truvada as PrEP can be negotiated

The Australian Government should rightly be concerned to achieve a fair price for Truvada as PrEP.

Truvada has been licensed in Australia since 2004 for the treatment of HIV infection. The provision of Truvada PrEP for HIV prevention purposes provides an opportunity for the negotiation of a fair price with its manufacturer. AFAO considers it reasonable that this price should be lower than the price negotiated for its treatment use, given the purpose of its use is different, it is not a new drug and the recovery of research and development costs by its manufacturer will have been satisfied through its HIV treatment indications.

AFAO notes that the patent for Truvada will expire in mid-2018, and is concerned that this may represent a closing window of opportunity for Truvada to be made available via the PBS since there will be diminishing incentive for the sponsor to go through costly re-submission processes should PBAC initially decline to recommend its listing on the PBS. Failure to achieve a timely listing would leave Australia in the unsatisfactory situation of having a safe and proven HIV prevention tool unavailable for an unknown period.

16. Proposed PBS clinical criteria

AFAO proposes the following clinical criteria for prescribing Truvada for PrEP through the PBS:

> Truvada for PrEP should be offered to any person who is assessed as being at high risk of acquiring HIV infection, taking into account risk factors arising from condomless anal or vaginal sex or injecting drug use.

Australia has excellent HIV epidemiological data and clinicians have access to expert guidance on PrEP prescribing. The Australian Society for HIV, Viral Hepatitis and Sexual Health (ASHM) has provided Australian Commentary on the United States PrEP Guidelines produced by the Centers for Disease Control. This guidance is available to clinicians to inform their decisions about whether patients should be prescribed PrEP, and PBAC should take comfort from the availability of this guidance. An expert panel of researchers and clinicians is currently working with ASHM to develop Australian clinical guidance on PrEP.

Use of post-exposure prophylaxis or, among men who have sex with men and transgender women, methamphetamine use or a recent sexually transmissible infection are markers of increased risk for HIV acquisition and people from these population groups reporting these behaviours should be considered for PrEP. These considerations can be addressed in Australian clinical guidance for PrEP prescribing.

17. Providing PBS access to PrEP can help end HIV transmission in Australia

There is strong recognition internationally that PrEP works and that its delivery needs to be integrated into health systems – to "put the strong and consistent evidence of PrEP efficacy into practice."[34]

Australia has a national, bipartisan commitment to the virtual elimination of HIV transmission in Australia by 2020. PrEP is a powerful HIV prevention tool, and facilitating its use has the potential to break the back of HIV transmission among gay men in Australia. With effective targeting of gay men most at risk of HIV and with equitable access for others at high risk of HIV, Australia can dramatically drive down HIV infection rates. We have the systems and infrastructure in place – not least through our community AIDS Councils and community networks – to integrate PrEP education and health promotion resources into existing education and care arrangements.

For Australia, TGA approval of use of Truvada as PrEP is just the first step. PrEP needs to be listed on the PBS if we are to end HIV transmission in Australia.

[34] "Pre-exposure prophylaxis works – it's time to deliver". The Lancet. Vol 385. April 18 2015, p. 1483.