Comments to the Pharmaceutical Benefits Advisory Committee

Gilead and Alphapharm HIV pre-exposure prophylaxis applications

AUSTRALIAN FEDERATION OF AIDS ORGANISATIONS
Leading the community response to HIV

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 infections and increase the percentage of people with HIV on antiretroviral treatment (ART).

Australia has a **national, bipartisan commitment** to these goals, with all Health Ministers endorsing them in a Council of Australian Governments (COAG) Standing Council on Health communique issued in 2013.

There has been **good progress on increasing treatment rates** for people living with HIV, but **little progress on reducing national infection rates**. In 2015 there were 1,025 HIV notifications, with gay and other men who have sex with men accounting for 68 per cent of these diagnoses.[2] This figure is consistent with the trend over the last decade.

In April 2017, another COAG communiqué from Australian Health Ministers recognised Pre- Exposure Prophylaxis (PrEP) as a crucial component for achieving Australia's goal of virtually eliminating HIV transmission by 2020.[3]

PrEP is potentially a **game-changer** that will make reaching Australia's 2020 HIV prevention target possible – but only if PrEP is accessible and affordable for those at high 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.[4] Conservative analysis by the Kirby Institute for Infection and Immunity in Society 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.

The TGA's registration of Gilead and Alphapharms' PrEP medications on the Australian Register of Therapeutic Goods is welcome, but **the cost of PrEP remains prohibitive** for most people.

The cost of providing 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 compared to the cost of lifetime treatment of that individual if they acquire HIV. The cost of providing PrEP under the PBS to those at high risk of HIV infection would be more than offset by **savings from HIV infections averted.**

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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 2016. The Kirby Institute, UNSW Australia.

3 Available at: http://www.coaghealthcouncil.gov.au/Portals/0/Final%20CHC%20Communique_24%20March%202017_1.pdf

4 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)

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, other community based HIV organisations and research organisations involved in PrEP demonstration projects in Australia are already providing **PrEP education resources** that emphasise the importance of daily adherence and recommend strategies to help users remind themselves to take PrEP.[5] It will be straightforward for these communications to continue once PrEP is added to the PBS.

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[6] and the frequency of re-testing. Quarterly STI screening of PrEP users has the potential to significantly increase the early 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 recommended by the World Health Organisation as a key HIV prevention tool**.

PrEP **prescribing arrangements need to be straightforward**. There is no clinical basis for placing an s100 restriction on prescribing arrangements for PrEP as the initiation of PrEP and ongoing monitoring is straightforward. Limitations on general practitioners prescribing PrEP may lead to delays in commencing PrEP, resulting in avoidable transmissions.

PrEP should be dispensed through **community pharmacies.**

A **fair price for PrEP** is essential. In the case of the two PrEP applications before PBAC, we believe that the PBS price should be informed by the price being paid by individuals to import PrEP from overseas suppliers of generic PrEP through the Personal Importation Scheme, and the price paid to purchase generic Truvada for clinical access programs in various Australian states.

AFAO, along with the National Association of People with HIV Australia, contributed to the development of the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine's 2017 Guidelines on PrEP. AFAO endorses these guidelines.

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."[7] 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

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5 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

6 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.

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

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community organisations and community networks – to integrate PrEP education and health promotion resources into existing education and care programs. Australia has demonstrated 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 HIV transmission in Australia by 2020.**

About AFAO

The Australian Federation of AIDS Organisations (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 Living with HIV Australia (NAPWHA); the Australian Injecting & Illicit Drug Users League (AIVL); the Anwernekenhe National HIV/AIDS Alliance (ANA); and Scarlet Alliance, Australian Sex Workers Association. AFAO advocates for its members, promotes medical and social research into HIV and its effects, develops and formulates policy on HIV issues, and provides HIV policy advice to Commonwealth, state and territory governments.

AFAO welcomes the opportunity to provide comment in support of the applications before PBAC to have HIV PrEP listed on the PBS.

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 Australia's commitment to the United Nations Political Declaration on HIV,[8] and in 2014, Australia's Health Ministers agreed to the goal of virtually eliminating new HIV infections in Australia by 2020. In April 2017, Australian Health Ministers released a joint communique in which they recognised PrEP as crucial to achieving the goal of eliminating HIV by 2020.[9] The communique acknowledged:

> ***"the importance of the consideration of listing of PrEP on the Pharmaceutical Benefits Scheme to ensure equitable and sustainable access for at-risk individuals in Australia for the prevention of HIV."***

There has been excellent progress on increasing treatment rates for people living with HIV, but little progress on reducing national infection rates. Over the three years from 2013 to 2015, the HIV infection rate in Australia remained stable. In 2015 there were 1,025 HIV infections newly diagnosed, with gay and other men who have sex with men accounting for 68 per cent of those diagnoses.[10]

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 PrEP on the PBS.

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

9 Available at: http://www.coaghealthcouncil.gov.au/Portals/0/Final%20CHC%20Communique_24%20March%202017_1.pdf

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

This submission focuses on how best to ensure that people at high risk of HIV are aware of PrEP as a prevention tool, and how PBS listing of PrEP is essential to efforts to substantially reduce HIV transmission in Australia.

2. Public health savings from infection averted

Aside from the individual benefit, there are considerable cost savings to the public health system from infections averted. A recent estimate of the average cost of treatment and care for one person is approximately $20,000 per year[11]. Epidemiological modelling indicates that if Australia achieved the target of 95 95 95[12] alongside a scale up 80% of men who have sex with men at high risk of HIV acquisition on PrEP by 2020, the number of men who will avoid acquiring HIV is: 184 people in the second half of 2017; 489 people in 2018; 613 people in 2019; and 739 people in 2020.[13] This is a total of 2,025 averted HIV infections by 2020.

The cumulative **savings from the infections averted** until 2020 **is $82 million**. The lifetime medical and treatment costs for a person living with HIV are estimated to be $1 million. The savings for preventing lifetime costs from all infections averted until 2020 is over $2 billion.

3. 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 four 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 prevention HIV.[14]

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11 This figure for treatment cost has been estimated by Dr Richard Gray from the Kirby Institute, UNSW. This figure is in 2015 dollars and is an average of treatments costs for the total population of HIV positive people who were diagnosed at different points in time. The figures for the different treatment costs come from the AFAO discussion paper: *Estimates of the number of people eligible for PrEP in Australia, and related cost-effectiveness* – attached as Appendix 1.

12 These numbers are 95% of people living with HIV diagnosed, 95% of people living with HIV on treatment and 95% on treatment and with an undetectable viral load. These numbers were adapted from UNAIDS targets

13 This is based on the assumption that by 2020 95% of all people living with HIV will know their HIV status, 95% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy, and 95% of all people receiving antiretroviral therapy will have viral suppression, which means that they cannot transmit HIV through sexual contact. Attached as Appendix 2 are the figures obtained from econometrician Dr Nick Scott from the Burnet Institute. The data cited here is drawn from that HIV incidence modelling.

14 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)

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. 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.

4. 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 a PrEP PBAC listing 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.

5. 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.[15] 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.[16] Gay and other homosexually active men who have heard of PrEP generally have a positive response to discussion of PrEP.[15]

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[17], PrEP'D for Change[18], and Time4PrEP[19]) working to promote and advocate for access, and to support gay men interested in accessing PrEP.

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15 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

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

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

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

19 For more information search Facebook: 'Time4PrEP'

6. 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.[20]

Real world considerations in making a decision whether or not to use PrEP include perceived self-risk of HIV acquisition, 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.[21]

Since then, a number of state-based PrEP demonstration projects have begun. The EPIC study in NSW enrolled 4385 gay and bisexual men at high risk of HIV between March and December 2016.[22] AFAO understands that as of May 2017 6000 people have enrolled in EPIC. In Victoria, enrolments in the PrEPX study has reached the cap of 3800 people, and in Queensland, QPrEP has enrolled over 1650 of the 2000 places in their study[24]. This indicates substantial interest in PrEP among gay and bisexual men at high risk of HIV.

7. Gay men in Australia are already using PrEP

The two 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 generic versions of Truvada for sale. These sites require an Australian-issued doctor's prescription.
  As discussed above in section 6, demonstration projects are in operation in a number of states and provide PrEP to considerable numbers of gay and bisexual men at high risk of HIV.

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 ensure the risk of harm is minimised.

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20 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.

21 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.
NSW Ministry of Health, NSW HIV Strategy 2016-2020: Data Report, Quarter 4 and annual. NSW Ministry of Health, available at: www.health.nsw.gov.au/endinghiv/Pages/tools-and-data.aspx

24 The HIV Foundation, PREP - Pre-exposure Prophylaxis, available at: http://hivfoundation.org.au/about-hiv/prevention/prep

8. Unmet need for PrEP

An AFAO report[25] estimates that there are 31,347 men who have sex with men at high risk of HIV acquisition who would be eligible for PrEP in Australia. This estimate is based on eligibility criteria contained in the 2017 ASHM Guidelines on PrEP. AFAO supports the ASHM guidelines and believes the eligibility criteria are well-considered and appropriately targeted. They are informed by finely calibrated understandings of HIV-transmission risk drawn from state-based the demonstration projects.

This estimate of 31,347 gay men and other men who have sex with men at high-risk of HIV acquisition indicates considerable need, which will be unmet, if PrEP is not listed on PBS. Current access arrangements are inequitable and will result in avoidable infections.

9. 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.

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.[26] Both VicPrEP and PrELUDE have reported therapeutic drug levels in individuals on PrEP. The VicPrEP study reports high-level adherence rates as assessed by self-reporting questionnaires, refill-based measures and dry-blood-spot assays of drug levels, with 90% of participants assessed as having therapeutic drug levels.[27]

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

The cost of PrEP remains prohibitive for most Australian gay men. If PrEP is not listed on the PBS, gay men who 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.

The burden of PrEP access currently sits with states and territories, an outcome that was never envisaged when the various Australian PrEP clinical trials were established over three years ago. The new PrEP eligibility estimates show a significantly higher number of people can benefit from PrEP than are catered for by the trials. These recently revised estimates reflect the considerable clinical, epidemiological and program knowledge gained since the first Australian PrEP trials commenced.

AFAO is also concerned that some state and territory governments who are supporting clinical trials might be unwilling to continue funding these trials if PBS listing does not occur within a reasonable timeframe. This outcome could lead to further inequitable access based on where people live and their ability to pay.

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[25] AFAO Discussion Paper: *Estimates of the number of people eligible for PrEP in Australia, and related cost-effectiveness* – attached as Appendix 1.

[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

[27] Lal L, Audsley J, et al. Medication adherence, condom use and sexually transmitted infections in Australian PrEP users: interim results from the Victorian PrEP Demonstration Project. *AIDS*. Advance online publication. 2017. https://www.ncbi.nlm.nih.gov/pubmed/28463880

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.[28] The PrEP demonstration projects have found that they are diagnosing HIV infections during enrolment, indicating that at-risk individuals are self-selecting for PrEP.

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

Gay men's sexual practices, as for most adults, vary 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 PrEP to a person during periods when they are at high-risk of acquiring HIV is minimal when compared to the lifetime treatment and medical costs incurred by individuals living with HIV. AFAO is cognisant of the cost-benefit consideration that PBAC is required to make. As discussed in section 2, on the basis of 80% of men who have sex with men at high risk of HIV acquisition being on PrEP by 2020, the number of men who will avoid acquiring HIV is: 184 people in 2017; 489 people in 2018; 613 people in 2019; and 739 people in 2020.[29] The cumulative savings from the infections averted for this group of men until 2020 is $82 million. Given that lifetime medical and treatments costs for HIV are estimated to be $1 million, the potential savings for the health budget are $2 billion.

We strongly encourage PBAC to recognise the nature of HIV as a communicable disease. Every HIV infection averted prevents onward transmission. In this way, PrEP must be considered as a public health intervention providing not only personal protection from HIV, but also as an intervention that has a population wide impact of 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. Rapid-scale of PrEP is required to maximise PrEP's impact as an HIV prevention tool. This rapid scale up can only be achieved if PrEP is access through the PBS.

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[28] 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

[29] This is based on the assumption that by 2020 95% of all people living with HIV will know their HIV status, 95% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy, and 95% of all people receiving antiretroviral therapy will have viral suppression, which means that they cannot transmit HIV through sexual contact. Attached as Appendix 2 are the figures obtained from econometrician Dr Nick Scott from the Burnet Institute, Victoria. The data cited here is drawn from that HIV incidence modelling.

12. 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.

Side effects for people using PrEP are usually transient. For sexually active gay men who use PrEP, ongoing clinical care will help with the management of any side effects, adherence and STI screening.

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.[30] It will be straightforward for these communications to continue once PrEP is added to the PBS.

13. 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.

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.

[30] 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

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 3), 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.[31] 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.

14. 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.[32] Social research indicates that there is considerable room to improve comprehensive HIV/sexual health testing rates[33] 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.

15. 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.

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.[34] Kenya recently announced that it will be providing publicly subsidised access to PrEP across the country.[35]

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31 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

32 For more information: http://stipu.nsw.gov.au/wp-content/uploads/STIGMA_Testing_Guidelines_Final _v5.pdf

33 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.

34 See https://www.england.nhs.uk/2016/05/prep-provision/

35 See http://www.nation.co.ke/news/Govt-launches-two-approaches-to-fight-HIV-Aids/1056-3914614-8p6ubc/

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.[36] 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.[37]

16. 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 man 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 PrEP as those that apply for prescribing of HIV treatments. Prescribing 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, 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. 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. This is vital if PrEP access is scaled up to ensure that the estimated number of men who are eligible for PrEP can access it.

PrEP should be dispensed through community pharmacies. Limitations on who can dispense PrEP will lead to unnecessary and avoidable transmissions. Like restrictions on prescribing ARV treatment, restricting those who can dispense PrEP, for example to hospital pharmacies, would present a significant barrier for people who do not have access to hospitals, including many people in rural and regional areas and some Aboriginal and Torres Strait Islander people who reside in remote communities.

17. A fair price for PrEP can be negotiated

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

[36] Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection what's new. World Health Organization, 2015.
[37] APCOM. PrEParing Asia. Meeting report.

Truvada, the patented drug approved for use as PrEP on the ARTG was approved for the treatment of HIV infection on the ARTG in 2004. The provision of Truvada as PrEP for HIV prevention purposes provides an opportunity for the negotiation of a fair price with its manufacturer. AFAO considers that a reasonable 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.

In relation to Alphapharm's submission, AFAO considers a fair price to be one that is informed by the price being paid by individuals to import PrEP from overseas suppliers of generic PrEP through the Personal Importation Scheme, and the price paid to purchase generic Truvada for clinical access programs in various Australian states.

18. Proposed PBS clinical criteria

Australia has excellent HIV epidemiological data and clinicians have access to expert guidance on PrEP prescribing. This year, ASHM approved the 2017 ASHM Guidelines on PrEP. 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. AFAO contributed to the development of ASHM's 2017 Guidelines on PrEP and endorses these Guidelines.

19. From PBAC approval to access through PBS

The PBAC should take all necessary steps to ensure that PrEP is accessible through the PBS as quickly as possible.

20. 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."[38]

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.

Access to PrEP in Australia is inconsistent. To ensure PrEP access is affordable and equitable, PrEP needs to be listed on the PBS.

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