



ashm

Supporting the HIV, Viral Hepatitis and Sexual Health Workforce

Australian Commentary

US Public Health Service Clinical Practice Guidelines on Prescribing PrEP

Welcome to the Australian Commentary

Research evidence about PrEP efficacy and safety

Human studies of blood-borne [1] and perinatal transmission [2], as well as studies of vaginal and rectal exposure among animals [3] provided suggestive data that antiretroviral drugs (ARVs), used as preexposure prophylaxis (PrEP), could reduce the risk of HIV infection through sexual and drug-use exposures. The efficacy of PrEP has now been established by a number of randomised placebo-controlled clinical trials conducted in men who have sex with men [4], heterosexual adults [5, 6], and injecting drug users [7]. Daily PrEP consisting of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) is considered safe and effective to reduce the risk of HIV infection in high-risk adults who are able to take the medication correctly and consistently. Based on the above data [8], TDF/FTC (marketed by Gilead as Truvada) has been approved for use as PrEP by the US Food and Drug Administration. In June 2014, the US Public Health Service issued Clinical Practice Guidelines and an accompanying Providers' Supplement. These cover the use of PrEP in three population groups: homosexual men, high-risk heterosexuals and injecting drug users. [10] A summary of evidence on HIV incidence, PrEP efficacy, adherence, safety and side-effects and PrEP-associated viral resistance [8] from clinical trials among men who have sex with men (MSM), heterosexual men and women and injecting drug users is included in Appendix 1 to [the US Public Health Guidelines](#).

Clinical trials have observed substantial variation in the efficacy of PrEP. Much of this is due to variation in adherence to study medication. However, high adherence-adjusted efficacy of around 92% in homosexual men and 84% in heterosexuals has been calculated. The safety profile of daily TDF/FTC use for HIV negative individuals is known from clinical trials with follow-up of participants from 1 to 4 years, but toxicity risks from longer term use in HIV negative individuals remains unknown. Adverse reactions are described in detail in the [TDF/FTC prescribing information from Gilead](#). Tenofovir use has been associated with renal tubular dysfunction including Fanconi's syndrome and progressive decline in renal function, particularly in patients of low body weight, which may be underestimated in shorter clinical trials. Monitoring for renal dysfunction including proteinuria when using Tenofovir for PrEP is advised [2].

At the moment, the only agents with evidence of efficacy as PrEP are TDF with or without FTC. Research continues on the development of the next generation of PrEP. The new research directions cover new ARV options, schedules of use and delivery mechanisms. In Australia,

neither TDF/FTC nor any other anti-retroviral agent has been licensed for preventive use yet. However, Australia maintains high commitment to reducing rates of HIV infection and PrEP use is commencing within several Australian states, initially as part of observational research studies (demonstration projects). The findings of these studies and those of relevant overseas studies and trials will inform the review and development of Australian PrEP prescribing guidance over the next few years.

PrEP in Australian Context

Truvada was licensed by the United States Food and Drug Administration (FDA) in July 2012 for use as PrEP in HIV negative individuals at high risk of acquiring HIV infection. Truvada is not licensed by the Therapeutic Goods Administration (TGA) for use as PrEP in Australia and is therefore not available at a subsidised price through Australia's Pharmaceutical Benefits Scheme (PBS). ASHM and community partners are urging Gilead Pharmaceuticals, who manufacture Truvada, to apply for TGA licensing as soon as possible. However, a TGA decision on such an application is unlikely to be made until at least 12 months after it has been lodged.

Victoria, New South Wales and Queensland have established access programs to provide Truvada to individuals at high risk to HIV infections. Places in these programs are capped and only available for residents of these three States. Truvada is being provided free of charge in these access programs – although a dispensing fee may be charged as for most other PBS medicines. If places in these access programs are not available, clinicians may wish to consider prescribing Truvada “off label” which involves asking the local supplier, Gilead Pharmaceuticals Australia, to supply the drug via an “off label” prescription. The cost is approximately \$13,500 for a 12 month supply of Truvada.

Another option is for patients to purchase generic Truvada from a reliable overseas supplier and import it under Australia's Personal Importation Scheme for Medicines (IPU). The cost of generic Truvada is considerably less (approximately \$1300 for 12 months) than for the brand-name.

Under the IPU scheme (<http://www.tga.gov.au/consumers/import.htm#VBe7B-kcTq4>), patients can legally import most medicines for their personal use. This involves arranging from within Australia for a medicine to be sent to the patient from an overseas supplier or family/friend. The medicines are only to be used by the patient (or a member of their immediate family) and must not be supplied to any other person. It is important to note that such medicines may not be approved for supply in Australia by the TGA; and the TGA warns there are no guarantees about their safety or quality. Subject to satisfying various conditions, patients may import a **3 month supply** (at the maximum dose recommended by the manufacturer) of an unapproved medicine without any prior approval required by the TGA.

Medicines ordered over the internet require an Australian-issued doctor's prescription. So to purchase or import Truvada into Australia, patients must first get a valid Australian-issued prescription from their doctor to accompany the medicine being imported. The internet can offer patients a convenient and less expensive way to access medicines. However, online purchases of medicines must be approached with caution. Medicines available on international websites are not regulated by the TGA. It is imperative to ensure that the website is legitimate, otherwise patients face risks, including that medicines are fake, past their use-by date or not manufactured to appropriate standards.

Patients must be advised that medical guidance from the Internet should never replace consultation with their doctor and should be interpreted with caution. Early data from the Victorian Pre-Exposure Prophylaxis Project (2015) report that people presenting for PrEP in Australia show a high rate of sexually transmitted infections at baseline (>25%) and that at least 1 in 100 people presenting for PrEP are already HIV positive. Appropriate clinical evaluation and ongoing care and monitoring are necessary to optimise the preventative effect of PrEP.

Further information on Truvada for PrEP can be obtained from local HIV clinics and organizations.

The Australian Commentary

The Australian Commentary outlines the ASHM recommendations on how to effectively implement the US Public Health Service Guidelines in Australia. This Commentary is embedded in [the US Public Health Service Clinical Practice Guidelines](#).

The intended users of this guideline include **s100 prescribers**.

Every presentation with a request for PrEP should be assessed as to the person's eligibility for PrEP, and the decision to prescribe PrEP should be based on the balance of the potential harms and benefits of using a prescribed medication for primary HIV prevention purposes.

The advice provided is necessarily general. The Australian commentary is intended to provide guidance which is appropriate to the majority of cases where PrEP is indicated to reduce significant ongoing risk of acquiring HIV. However, ultimately the decision to prescribe PrEP needs to be made on a case-by-case basis considering the context in which patients may be placing themselves at risk of acquiring HIV. Any unusual or complex case should be discussed with an expert in HIV medicine before deciding whether or not PrEP should be prescribed.

Links

US Public Health Service Clinical Practice Guidelines
www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

US Public Health Service Clinical Practice Guidelines—Providers' Supplement
www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf

References

1. Cardo, D.M., et al., *A case-control study of HIV seroconversion in health care workers after percutaneous exposure*. *Centers for Disease Control and Prevention Needlestick Surveillance Group*. *N.Engl.J.Med.*, 1997. **337**(21): p. 1485-1490.
2. Chemther, J.I. 2014 Dec;20(12):784-8. doi: 10.1016/j.jiac.2014.08.015. Epub 2014 Oct 7. *AIDS*. 2014 Aug 24;28(13):1903-10.
3. Connor, E.M., et al., *Reduction of Maternal-Infant Transmission of Human-Immunodeficiency-Virus Type-1 with Zidovudine Treatment*. *New England Journal of Medicine*, 1994. **331**(18): p. 1173-1180.
4. Garcia-Lerma, J.G., et al., *Prevention of rectal SHIV transmission in macaques by daily or intermittent prophylaxis with emtricitabine and tenofovir*. *Plos Medicine*, 2008. **5**(2): p. 291-299.
5. Grant, R.M., et al., *Preexposure chemoprophylaxis for HIV prevention in men who have sex with men*. *N.Engl.J.Med.*, 2010. **363**(27): p. 2587-2599.
6. Baeten, J.M., et al., *Antiretroviral prophylaxis for HIV prevention in heterosexual men and women*. *N Engl J Med*, 2012. **367**(5): p. 399-410.
7. Thigpen, M.C., et al., *Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana*. *N Engl J Med*, 2012. **367**(5): p. 423-34.
8. Choopanya, K., et al., *Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial*. *Lancet*, 2013. **381**(9883): p. 2083-90.
9. Gridley, G., et al., *Incidence of cancer among patients with rheumatoid arthritis*. *J Natl Cancer Inst*, 1993. **85**(4): p. 307-11.
10. Gianella, S et al. *Future Virol.* (2013) 8:1037

Australian Commentary on the Preexposure Prophylaxis for the Prevention of HIV in the United States- 2014 – Clinical Practice Guideline

(Last updated: 16 February 2015; last reviewed: 16 February 2015)

Significant updates are highlighted throughout the [PDF version of the document](#) (these will hyperlink through to other support material).

Key Updates to Existing Sections

The following are key updates to existing sections of the US Public Health Service/CDC 2014 Clinical practice guideline on PrEP. The ‘Committee’ refers to the ‘ASHM Sub-Committee for Guidance on HIV Management’ who provide clinical oversight in the development of Australian Commentary on the US DHHS Antiretroviral Guidelines and these US Public Health Service/CDC 2014 Clinical practice guideline on PrEP.

[Table 1_Aus](#) to replace US CDC 2014 Table 1

Change in Intended Users of the Guideline

This change can be found in US CDC Guidelines section [Introduction](#) . In Australia, intended users of these guidelines are s100 prescribers.

Change in Behavioural Risk Assessment and Eligibility Criteria for PrEP

This change can be found in US CDC Guidelines section [Assessing risk of sexual HIV acquisition](#) and is summarised in [x1, x2, x3, x4, x5a, x5b](#)

Due to distinct differences between HIV epidemics in Australia and the US, including in risk factors involved in HIV transmission and HIV incidence and prevalence, the ‘Committee’ recommends using the information below to assess risk and determine the eligibility of your patient for PrEP.

The risk of HIV transmission through a single or multiple exposures is determined by:

- The nature of the exposure with its estimated risk per exposure ([Table x1_Aus](#))
- The number of such exposures
- The likelihood of the source being HIV positive, if their status is unknown ([Table x2_Aus](#))
- Factors associated with the source and exposed individuals ([Table x3_Aus](#)).

All sexual risk estimations are for unprotected sexual contact. It is assumed that a similar risk is incurred when a condom fails.

Table x1_Aus: Exposure and transmission risk/exposure with known HIV positive source

(Adopted from the national PEP guidelines. [1] In general, these estimates relate to populations where most individuals were not on ART).

Note: For more information, see Literature Review for the national PEP guidelines, section Transmission risks associated with different exposures [2]

Type of exposure with known HIV positive source	Estimated risk of HIV transmission/exposure
Receptive anal intercourse (RAI)	
– ejaculation	1/70
– withdrawal	1/155

Sharing contaminated injecting equipment	1/125
Insertive anal intercourse (IAI) uncircumcised	1/160
Insertive anal intercourse (IAI) circumcised	1/900
Receptive vaginal intercourse (RVI)	1/1250 ¹
Insertive vaginal intercourse (IVI)	1/2500 ¹
Receptive or insertive oral intercourse	Unable to estimate risk – extremely low
Needlestick injury (NSI) or other sharps exposure	1/440
Mucous membrane and non-intact skin exposure	< 1/1000

Table x2_Aus: HIV seroprevalence in Australian populations (adopted from the national PEP guidelines [1]).

Community group	HIV seroprevalence (%)
Homosexual men (MSM – men who have sex with men)	
• ACT	4.2
• Adelaide	5.4
• Brisbane	8.8
• Melbourne	8.1
• Perth	4.5
• Sydney	11.8
Actual seroprevalence may be higher than reported seroprevalence [8]	
Injecting drug users in Australia	
• homosexual	29.2
• all others	1.0
Heterosexuals in Australia	
• blood donors (% donations)	0.0004
• STI clinic attendees	<0.5
Commercial sex workers (Australia)	<0.1
Overall Australian seroprevalence	0.1

Table x3_Aus: Factors known to increase the risk of HIV transmission (adopted from the national PEP guidelines [1]).

- a higher plasma viral load (highest loads occur when seroconverting or with advanced disease);
- a sexually transmissible infection in the source or exposed individual, especially genital ulcer disease and symptomatic gonococcal infections;
- a breach in genital mucosal integrity (e.g., trauma, genital piercing or genital tract infection);
- a breach in oral mucosal integrity when performing oral sex;
- penetrating, percutaneous injuries with a hollow bore needle, direct intravenous or intra-arterial injection with a needle or syringe containing HIV infected blood;
- the uncircumcised status of the insertive HIV negative partner practising IAI or IVI.

Early initiation of antiretroviral therapy, compared with delayed therapy, resulted in a relative reduction of 96% in the number of linked HIV transmissions in serodiscordant heterosexual couples. Therefore the transmission risk for vaginal intercourse with an HIV positive partner with an undetectable viral load may be estimated to be decreased by a factor of 20. [3] As to the transmission risk through anal intercourse, the only evidence at the time of the publication of these guidelines comes from the interim analyses presented by the Partner Study [4]. The latter showed that, in serodiscordant couples, the rate of within-couple HIV transmissions during eligible couple-years was zero, however, the upper limits of the 95%CI were 0.96/100 CYFU for

¹ These estimates are based on prospective studies, not cross-sectional data or from modelling

anal sex (in gay and straight couples combined) and 1.97/100 CYFU for receptive anal sex with or without ejaculation (for gay couples).

Determining eligibility for PrEP

PrEP is indicated for HIV-negative adults who are at ongoing high risk for HIV infection. HIV-negative status should be confirmed as close to initiation of PrEP as possible, ideally on the same day but not more than 7 days before the prescription is given, by using the standard-of-care testing procedures.

PrEP is meant to be used by people who are at high and ongoing risk of acquiring HIV.

Table x4_Aus summarizes different practices and conditions associated with high HIV incidence among men who have sex with men.

Table x4_Aus: Different practices and conditions associated with high HIV incidence among MSM

Note: Data for this table were obtained from the Health in Men (HIM) study conducted during 2001-2007. Data were collected for six-month intervals. Due to the specifics of data collection for this study, not all indicators were available to support each individual eligibility criterion, and some indicators were collected in somewhat different form, have a different denominator or reference period.

Risk factor	Associated HIV incidence	
	Per 100 person-years	95% Confidence Interval
All patients regardless of practices	0.78	0.59-1.02
A. Highest risk		
A regular sexual partner of or having at least one episode of unprotected sex with an HIV-infected man with whom condoms were not consistently used in the last six months ²	5.36	2.78-10.25
At least one episode of receptive unprotected anal intercourse (CLAI) with any casual HIV-infected male partner or a male partner of unknown HIV status during the last six months	2.31	1.48-3.63
Rectal gonorrhoea diagnosis in last six months	7.01	2.26-21.74
Rectal chlamydia diagnosis in last six months	3.57	1.34-9.52
Methamphetamine use in last six months	1.89	1.25-2.84
B. Medium to high risk		
More than one episode of anal intercourse during the last 3 months when proper condom use was not achieved (e.g., condoms slipped off or broke)	1.30	0.95-1.77
A regular sexual partner of or having at least one episode of insertive CLAI where the serostatus of partner is not known or is HIV-positive ³	0.94	0.35-2.52
- In uncircumcised men	1.73	0.43-6.90
- In circumcised men (comparison group, low risk, PrEP not recommended)	0.65	0.16-2.61

Providers need to obtain a thorough sexual and drug-use history to determine PrEP eligibility and to regularly discuss high HIV-risk practices with their patients to assess continuing candidacy for PrEP. Behavioural eligibility criteria for PrEP prescription are outlined in Table 5a_Aus.

² Data used to generate this estimate did not include the treatment and viral load status of the HIV positive regular partner as this information was not available

³ The estimates produced by the HIM study cannot account for the treatment and/or viral load status of the HIV positive regular partner as this information was not collected

Table 5a_Aus: Behavioural eligibility criteria for PrEP: MSM

A. High risk - recommend prescribing daily PrEP if the client acknowledges:

being likely to have multiple events of condomless anal intercourse (CLAI), with or without sharing intravenous drug use (IDU), in the next 3 months (indicating sustained risk)

AND

Having any of the following:

- Regular sexual partner of an HIV-infected man with whom condoms were not consistently used in the last 3 months (HIV positive partner is not on treatment and/or has detectable viral load);
- At least **one** episode of receptive CLAI with any casual HIV-infected male partner or a male partner of unknown HIV status in the last 3 months;
- Rectal gonorrhoea, chlamydia and/or syphilis diagnosis during the last 3 months or at screening;
- Methamphetamine use in the last 3 months

B. Medium risk - consider prescribing daily PrEP if the client acknowledges:

being likely to have multiple events of CLAI, with or without sharing IDU, in the next 3 months (indicating sustained risk)

AND

Any of the following is reported

- More than one episode of anal intercourse in the last 3 months when proper condom use was not achieved (e.g., condoms slipped off or broke);
- if client is uncircumcised and reports more than one episode of insertive CLAI in the last 3 months where the serostatus of partner was not known or was HIV positive and not on treatment.

C. Low risk - PrEP is not recommended for individuals who:

- have no risk exposure other than CLAI with a partner with documented sustained undetectable HIV viral load in the previous 3 months. In this setting however, if the HIV+ partner has recurrent STIs PrEP may be considered.
- are circumcised and report practicing exclusively insertive CLAI in the last 3 months

Note: MSM who have only infrequent exposures to HIV (e.g., an occasional broken condom or lapse in condom use) may be good candidates for nPEP rather than PrEP. These men, as well as men who fall into low risk category C, should be educated about safer sex strategies, nPEP and PrEP, and decision about PrEP use should be made on a case by case basis.

Table x5b_Aus: Behavioural eligibility criteria for PrEP: heterosexual men and women

A. High risk - recommend prescribing daily PrEP if the client acknowledges:

being likely to have multiple events of condomless anal or vaginal intercourse (CLAI or CLVI, respectively), with or without sharing IDU, in the next 3 months (indicating sustained risk)

AND

- Being a regular sexual partner of an HIV-infected man or woman with whom condoms were not consistently used in the last 3 months (HIV positive partner is not on treatment and/or has detectable viral load);

B. Medium risk - consider prescribing daily PrEP if:

- a female client is in serodiscordant heterosexual relationship and is planning natural conception in the next 3 months

C. Low risk - PrEP is not recommended for individuals who:

- have no risk exposure other than CLVI or CLAI with a partner with documented sustained undetectable HIV viral load in the previous 3 months. However, PrEP may be considered for a female client during a period around attempted conception.
- are a circumcised man who reports practicing exclusively CLVI in the last 3 months

Note: Heterosexual men and women who fall into low risk category C, should be educated about safer sex strategies, nPEP and PrEP, and decision about PrEP use should be made on a case by case basis.

Table x5c_Aus: Behavioural eligibility criteria for PrEP: people who inject drugs

A. High risk - recommend prescribing daily PrEP if the client acknowledges:

being likely to have multiple events of sharing needles or injecting equipment with an HIV positive individual or a homosexually active man and has inadequate access to safe injecting equipment in the next 3 months (indicating sustained risk)

AND

- Sharing needles or injecting equipment with an HIV positive individual or with a homosexually active man in the last 3 months

Note: People who inject drugs and do not fall into high risk category as per criteria above should be educated about safe injecting and sex practices, nPEP and PrEP. In these cases and particularly in population s with a higher proportion of HIV cases due to injecting drug use such as indigenous people, decisions about PrEP use should be made on a case by case basis.

Along with encouraging safer-sex practices and safer injection techniques (if applicable), clinicians should assist their patients in making a decision of when to use PrEP and when to discontinue its use.

The length of PrEP use will depend on the individual's continuing risk practices over time. PrEP should only be prescribed to those patients who are prepared to adhere to the regimen and express a willingness to do so.

Information and guidance around the clinical evaluation and care of people who choose to use PrEP should be tailored to meet the needs of different health professionals involved in the PrEP care pathway. As a corollary, health and community peak bodies and health care professionals involved in the provision of PrEP should tailor the information to meet the needs of different at-risk target groups within Australia.

References

1. ASHM Post-Exposure Prophylaxis after Non-Occupational and Occupational Exposure to HIV: National Guidelines. Australian Government Department of Health and Aging, 2013.
2. Savage J and the National PEP Guidelines Reference Group. Literature review for the National guidelines for post-exposure prophylaxis after non-occupational and occupational exposure to HIV. [monograph on the internet] Australasian Society for HIV Medicine: Sydney, 2012. Available from www.ashm.org.au/pep-guidelines
3. Cohen, M.S., et al., Prevention of HIV-1 Infection with Early Antiretroviral Therapy. N.Engl.J.Med., 2011. **365** (6): p. 493-505.
4. Rodger A. HIV transmission risk through condomless sex if HIV+ partner on suppressive ART: PARTNER Study. 21st CROI, 3-6 March 2014, Boston. Oral late breaker abstract 153LB. <http://www.croiwebcasts.org/console/player/22072>.

Change in Testing for HIV

This change can be found in US CDC Guidelines section Laboratory Tests and other Diagnostic Procedures

In Australia, the required HIV testing should be accomplished by drawing blood (serum) and sending the specimen to a laboratory for a 4th generation HIV 1/2 Ag/Ab Combo assay plus Western Blot for confirmation. No point-of-care rapid tests should be used. Clinicians should not accept patient-reported test results or documented anonymous test results. A preliminary positive HIV antibody test must be confirmed by Western blot or pro-viral DNA test according to the local laboratory standard practice and viral load and CD4 lymphocyte tests should be ordered to assist in future treatment decisions. [1,2]

References:

1. Australian Society for HIV Medicine. [Australian Sexually Transmitted Infections & HIV Testing Guidelines for Asymptomatic MSM 2014](http://www.ashm.org.au). Available online at <http://www.ashm.org.au>.
2. Australian Society for HIV Medicine. Antiretroviral guidelines. US DHHS guidelines with Australian commentary. Available online at <http://arv.ashm.org.au>.

A footnote has also been included with the following text under the Figure Documenting HIV Status. In Australia, no point-of-care rapid tests should be used for determining HIV status of patients who are assessed for eligibility for PrEP. All such patients should be assessed using a 4th generation HIV 1/2 Ag/Ab Combo assay.

Change in Assessment of Renal Function:

Renal evaluation before initiation and while on Tenofovir treatment for PrEP should include a urine albumin: creatinine ratio (ACR), serum creatinine, eGFR, and blood pressure measurement. Other renal risk factors should be taken into account when deciding to prescribe Tenofovir including co-administration of other nephrotoxic agents. While on Tenofovir, urine ACR and the eGFR should be assessed on a 6 monthly basis and if proteinuria occurs or decline in eGFR is noted, cessation of PrEP should be considered.

In Australia the recommended equation to evaluate the eGFR is the CKD-EPI formula (see Kidney Health Australia for reference: <http://www.kidney.org.au/HealthProfessionals/DetectingCKD>).

eGFR (using the CKD-EPI equation) is recommended to be automatically reported by all Australian pathology laboratories with every request for serum creatinine in individuals aged 18 or over. It can also be calculated by using an online [GFR \(CKD-EPI formula\) Calculator](#). Any person with an eGFR of <60 ml/min should not be prescribed PrEP with TDF/FTC.

Change in Contact tracing for HIV seroconverters:

On page 40, the US guidelines recommend: "Assistance with, or referral to, the local health department for the identification of sex partners who may have been recently exposed to HIV so that they can be tested for HIV infection, considered for nonoccupational postexposure prophylaxis (nPEP), and counselled about their risk-reduction practices".

In this instance, [Australian contact tracing guidelines](#), as contained in the STI management guidelines, should be followed.

Change in Patients with Chronic active hepatitis B or C virus infection:

In reference to the following text in the US guidelines: "For clinicians without this experience, co-management with an infectious disease or a hepatic disease specialist should be considered. Patients should be tested for HBV DNA by the use of a quantitative assay to determine the level of HBV replication [99] before PrEP is prescribed and every 6-12 months while taking PrEP", the Committee has agreed to the management of chronic hepatitis B infection in line with the [Chronic Hepatitis B Management Recommendations](#), GESA Digestive Health Foundation, 2009/10".

Change to Non-occupational postexposure prophylaxis:

In reference to the US guidelines section on Non-occupational Postexposure Prophylaxis, the Committee agreed that:

If there has been a significant HIV exposure within the last 72 hours, and the person is determined not to have HIV infection, clinicians should offer nPEP which should be started immediately as per National guidelines for Post-exposure prophylaxis after non-occupational and occupational exposure to HIV (2013) [1] and transitioning to PrEP if indicated after completion of the 28-day course of nPEP.

Reference:

1. Australian Society of HIV Medicine. Post-exposure prophylaxis after non-occupational and occupational exposure to HIV: National guidelines (2013). Available online at <http://www.ashm.org.au>.

Change in Financial case management issues for PrEP :

Since financial issues of PrEP provision are specific to the local context, this section is not relevant in Australia.

Change in Reference to HIV testing sites:

For further information about HIV testing in Australia visit [ASHM](#) or [Australian Government Department of Health and Ageing](#)

Changes to Training and technical assistance in providing components of PrEP-related services, medications, and counselling are available

In Australia, for information about local PrEP related services visit:

ASHM: <http://www.ashm.org.au>

ACON: <http://www.acon.org.au>

AFAO: <http://www.afa.org.au>

NAPWHA: <http://napwha.org.au>

Related DHHS guidelines

In Australia, further guidance can be found in the following documents posted on the ASHM website at <http://www.ashm.org.au>:

- [Australian STI management guidelines for use in primary care](#)

- The US DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents and the [Australian Commentary on the DHHS Guidelines](#) released on the 13 February 2013
- Post-exposure prophylaxis after non-occupational and occupational exposure to HIV: National guidelines (2013)
- 2014 National HIV Testing Policy v1.0
- [2012 National HBV Testing Policy v1.1](#)
- [2012 National HCV Testing Policy v1.1](#)
- STIGMA guidelines