



3. Indications for PrEP in Australia

HIV epidemiology

Australia has a concentrated human immunodeficiency virus (HIV) epidemic, whereupon in 2018 sexual contact between men accounted for approximately 70% of new HIV diagnoses (1). During 2018, 23% of new diagnoses occurred in heterosexuals, and about one-third of these occurred where the person, or their partner came from a country with high HIV prevalence. Only 3% of new HIV diagnoses were attributable to injecting drug use alone.

Overall, the annual number of HIV diagnoses in Australia declined by 23% during 2014-2018 (1), and this decrease was attributable to a 30% decline in notifications among men who have sex with men (MSM). There was no decline in HIV in Aboriginal and Torres Strait Islander people (hereafter referred to as Indigenous), in heterosexual people or in those born overseas.

In MSM, an 11% decline in HIV notifications was observed over five years between 2013 and 2017, but the decline increased to 15% in 2016-2017. However, this decline in HIV diagnoses among MSM was not uniform. In the last 10 years, notifications declined by 21% in Australian-born MSM, while the proportion of notifications almost doubled (from 28% to 52%) among overseas-born MSM (1). The estimated proportion of undiagnosed HIV was also high among people born in Southeast Asia (27%) (1). The uptake of HIV pre-exposure prophylaxis (PrEP) remained low in this population, comprising only 9% of PrEP participants in the EPIC NSW trial (2). In Victoria, the incidence of HIV infection in newly arrived Asian-born MSM attending a sentinel sexual health clinic did not decline during 2013-2017 whereas the incidence fell by 45% in Australian-born MSM attending the same site (3).

A 10% increase in HIV notifications of heterosexual exposure was reported between 2013 and 2017, with a 14% increase between 2016 and 2017, which was mainly attributed to the increase in the number of notifications among Australian-born men over these time periods (37% and 31%, respectively) (1). In women, the notification rate remained stable during 2013-2017 (between 0.7 and 0.9 per 100,000), however, was low compared with that in men (0.9 vs 7.1 per 100,000 in 2017).

In the Indigenous population the rate of HIV notifications increased by 41% between 2013 and 2016, compared with a 12% decline in Australian-born non-Indigenous people, and in 2017 was 1.6 times higher than in the Australian-born non-Indigenous population (1). During 2015-2017, more HIV notifications in the Indigenous population were attributed to heterosexual sex (21%) and injecting drug use (18%) than in the Australian-born non-Indigenous population (18% and 3%, respectively).

Among female sex workers, HIV incidence remained stable at or below 0.13 per 100 person-years during 2013-2017, and was 0.13 per 100 person-years in 2017 (1). Similarly, for people who inject drugs (PWID), HIV prevalence has remained low in the past 10 years and ranged between 1.0% and 2.1% among people attending needle and syringe programs (2.1% in 2017), and 0.7% if gay and bisexual men were excluded

from the sample. However, prevalence of HIV among Indigenous men in these programs has increased almost five times between 2010–2011 and 2016–2017 from 0.9% to 4.2% (1).

HIV prevention

Overall, recent declines in HIV incidence and notifications concurred with Initiatives focused on improved uptake in HIV testing and treatment with simpler HIV treatment regimens. Consequently, 74% of people living with HIV in 2017 reached viral load suppression, thereby achieving zero risk of onward HIV transmission (1).

By the end of 2018, 18,530 people, of whom 99% were male, were receiving Pharmaceutical Benefits Scheme (PBS)-subsidised PrEP in Australia (4). Largely related to PrEP implementation, a 25% decline in new HIV diagnoses was observed among MSM in New South Wales, from 295 in the 12 months before the Expanded PrEP Implementation in Communities New South Wales (EPIC-NSW) study commenced to 221 in the 12 months following study commencement (2).

As described above, HIV notifications in Indigenous populations increased by 41% between 2013 and 2016 and diverged from the trends in the Australian-born non-Indigenous population (1). This divergence in HIV rates between the two populations possibly relates to a number of factors including a higher proportion of undiagnosed cases of HIV in the Indigenous population, sexual and drug-injecting practices and, importantly, a slower adoption of biomedical prevention strategies such as treatment as prevention and PrEP (5). Hence intensive HIV prevention and treatment efforts, including the use of PrEP, are required to reverse this alarming trend (6).

There are no available recent data about HIV testing uptake and access to antiretroviral drugs for PrEP for temporary residents who are ineligible to access Medicare (including short-term visitors, international students, skilled workers and some temporary residents awaiting decisions regarding their permanent residency as partners of citizens or permanent residents, asylum seekers and refugees).

In other population groups, harm reduction strategies for PWID and HIV and sexually transmissible infection (STI) prevention strategies for sex workers have been highly successful in keeping the prevalence and incidence of HIV at extremely low levels in Australia and among the lowest in the world. Current health promotion and HIV prevention strategies support PWID and sex workers to maintain these achievements, while access to PrEP may expand HIV prevention options (7).

HIV risk categories and targeted availability of PrEP in Australia

Informed by the local epidemiology of HIV, access to PrEP in Australia has been pragmatically targeted to MSM at increased risk of HIV acquisition. Criteria for increased HIV risk were originally defined based on the evidence from the Sydney-based Health in Men (HIM) study (8).

The [Table 3.1](#) summarises the main factors associated with an increased risk of HIV acquisition among gay and bisexually identified men in the Sydney-based HIM study (8). Four factors were associated with HIV incidence of above 1.8 per 100 person-years; these factors formed the criteria for identifying people at high risk of HIV acquisition. Two more factors with an HIV incidence above 1.0 and below 1.8 per 100 person-years formed the criteria for identifying people at medium HIV acquisition risk. Although the HIM study

collected data from 2001 to 2007 and HIV notification trends have changed since then, the same factors are likely to remain relevant to HIV transmission and its prevention today, and these factors were validated as eligibility criteria in an analysis of data from the Victorian PrEPX study (9) and continue to guide PrEP prescribing throughout Australia.

Risk factor	HIV incidence per 100 person years (95% CI)
All gay and bisexual men regardless of behavioural practices	0.78 (0.59–1.02)
A regular sexual partner of an HIV-positive man with whom condoms were not consistently used in the last 6 months	5.36 (2.78–10.25)
At least one episode of receptive, unprotected anal intercourse with any casual male partner with HIV infection or a male partner of unknown HIV status during the last 6 months	2.31 (1.48–3.63)
Rectal gonorrhoea diagnosis in last 6 months	7.01 (2.26–21.74)
Rectal chlamydia diagnosis in last 6 months	3.57 (1.34–9.52)
Methamphetamine use in last 6 months	1.89 (1.25–2.84)
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 CLAI or having at least one episode of insertive CLAI where the serostatus of partner is not known or is HIV positive	0.94 (0.35–2.52)
In uncircumcised men having at least one episode of insertive CLAI where the serostatus of partner is not known or is HIV positive	1.73 (0.43–6.90)
In circumcised men (comparison group, low risk, PrEP not recommended)	0.65 (0.16–2.61)

Table 3.1 Factors associated with elevated risk of HIV acquisition among men who have sex with men in the Health in Men (HIM) study, Australia, 2001–2007 (8)

Note that while the HIM study uses the terminology of ‘gay and bisexual men’, this guideline uses ‘men who have sex with men’ to focus on behaviour, rather than identity

CI: confidence interval; CLAI: condomless anal intercourse; HIV: human immunodeficiency virus; PrEP: pre-exposure prophylaxis

Of note, due to the specifics of data collection for the HIM study, not all indicators were available to support each individual eligibility criterion for PrEP. Some indicators were collected in different forms, or had a different denominator or reference period. Most importantly, the HIV viral load of HIV-positive regular partners is now known to have a significant impact on HIV transmission (10–12), and data on the HIV viral load of the source partners were not collected in the HIM study. Similarly, infectious syphilis was uncommon in the HIM cohort and was not associated with HIV transmission. However, its incidence has increased greatly since 2007 in Australia. Syphilis is associated with an increased risk of HIV among MSM globally (13, 14), and is therefore included in the PrEP suitability assessment. Drug use is another important factor that influences sexual behaviour and HIV risk acquisition and that has emerged since the HIM study. Methamphetamine use has been associated with increased risk of HIV infection in high-income countries internationally (15). In Australia associations have been observed between injecting drug use and sexual risk taking (16) with a higher incidence of drug use initiation occurring in younger versus older MSM (17).

Finally, the reference period for PrEP suitability assessment is set up in these guidelines to reflect behaviour over the previous 3 months whereas the HIM study addressed behaviour over the previous 6 months (8). In addition, the epidemiology of drug use has changed in MSM in Australia (15-19).

The 2017 ASHM PrEP guidelines classified a person's risk of HIV acquisition as high or low based on criteria from the HIM study (8). The 2017 guidelines recommended that an individual had to report HIV risk in the 3 months before commencing PrEP and that the individual anticipated that they would have HIV risk in the 3 months after commencing PrEP. Individual's risk of HIV acquisition were classified as high or low based on evidence from the HIM study (8). Additionally, in the 2017 guidelines, clinicians were invited to consider offering PrEP on a case-by-case definition to people who did not meet high- or medium-risk criteria.

Importantly, the 2019 ASHM PrEP guidelines no longer classify a person's risk of HIV acquisition as high or low and no longer require that an individual demonstrate HIV risk in the previous 3 months. Instead the 2019 guidelines provide behavioural examples of what would make a person suitable for PrEP, including whether a person's quality of life would be likely to improve if they were offered PrEP, e.g. people with high levels of anxiety about HIV acquisition. (see [Suitability for PrEP](#)).

Overall, the epidemiological data highlight the need to strengthen the current strategies for HIV prevention especially in Indigenous populations, overseas-born MSM where HIV rates are rising and heterosexuals, which would include expanding and promoting the uptake of PrEP by all eligible people.

The PrEP suitability criteria that are provided in these guidelines are not intended to limit or deny access to PrEP to any person who seeks it. Instead, they are intended to help identify and actively recommend PrEP to people suitable for PrEP and to guide clinicians in their discussions about PrEP with patients who are uncertain about their HIV risk and need for PrEP use (see [Suitability for PrEP](#)).

References

1. Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia: annual surveillance report 2018. Sydney: Kirby Institute, UNSW Sydney; 2018. Available at: <https://kirby.unsw.edu.au/report/hiv-viral-hepatitis-and-sexually-transmissible-infections-australia-annual-surveillance> (last accessed 27 August 2019).
2. Grulich AE, Guy R, Amin J, et al; Expanded PrEP Implementation in Communities New South Wales (EPIC-NSW) research group. Population-level effectiveness of rapid, targeted, high-coverage roll-out of HIV pre-exposure prophylaxis in men who have sex with men: the EPIC-NSW prospective cohort study. *Lancet HIV* 2018;5:e629-37.
3. Medland NA, Chow EPF, Read THR, et al. Incident HIV infection has fallen rapidly in men who have sex with men in Melbourne, Australia (2013–2017) but not in the newly arrived Asian-born. *BMC Infect Dis* 2018;18:410.
4. Kirby Institute. Monitoring HIV pre-exposure prophylaxis uptake in Australia. PBS-subsidised HIV pre-exposure prophylaxis from April 2018 to December 2018. Issue 1. 1 June 2019. Sydney: The Kirby Institute, UNSW Sydney; 2019. Available at: https://kirby.unsw.edu.au/sites/default/files/kirby/report/Monitoring-HIV-PrEP-uptake-in-Australia-newsletter_Issue1.pdf (last accessed 3 September 2019).
5. Kirby Institute. Bloodborne viral and sexually transmissible infections in Aboriginal and Torres Strait Islander people: annual surveillance report 2018. Sydney: Kirby Institute, UNSW Sydney; 2018.
6. Ward JS, Hawke K, Guy RJ. Priorities for preventing a concentrated HIV epidemic among Aboriginal and Torres Strait Islander Australians. *Med J Aust* 2018;209:56.
7. Heard S, Iversen J, Geddes L, Maher L. Australian NSP Survey National Data Report 2013-2017: prevalence of HIV, HCV and injecting and sexual behaviour among NSP attendees. Sydney: Kirby Institute, UNSW Sydney; 2018.
8. Poynten IM, Jin F, Prestage GP, Kaldor JM, Kippax S, Grulich AE. Defining high HIV incidence subgroups of Australian homosexual men: implications for conducting HIV prevention trials in low HIV prevalence settings. *HIV Med* 2010;11:635-41.
9. Cornelisse VJ, Fairley CK, Stoope M, et al; PrEPX Study Team. Evaluation of preexposure (PrEP) eligibility criteria, using sexually transmissible infections as markers of human immunodeficiency virus (HIV) risk at enrollment in PrEPX, a large Australian HIV PrEP trial. *Clin Infect Dis* 2018;67:1847-52.
10. Cohen MS, Chen YQ, McCauley M, et al; HPTN 052 Study Team. Antiretroviral therapy for the prevention of HIV-1 transmission. *N Engl J Med* 2016;375:830-9.
11. Bavinton BR, Pinto AN, Phanuphak N, et al; Opposites Attract Study Group. Viral suppression and HIV transmission in serodiscordant male couples: an international, prospective, observational, cohort study. *Lancet HIV* 2018;5:e438-47.
12. Rodger AJ, Cambiano V, Bruun T, et al; PARTNER Study Group. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. *Lancet* 2019;393:2428-38.
13. Darrow WW, Echenberg DF, Jaffe HW, et al. Risk factors for human immunodeficiency virus (HIV) infections in homosexual men. *Am J Public Health* 1987;77:479–83.

14. Hook EW 3rd. Syphilis. *Lancet* 2017;389:1550–57.
15. Vu NT, Maher L, Zablotska I. Amphetamine-type stimulants and HIV infection among men who have sex with men: implications on HIV research and prevention from a systematic review and meta-analysis. *J Int AIDS Soc* 2015;18:19273.
16. Bui H, Zablotska-Manos I, Hammoud M, et al. Prevalence and correlates of recent injecting drug use among gay and bisexual men in Australia: results from the FLUX study. *Int J Drug Policy* 2018;55:222-30.
17. Jin F, Hammoud MA, Maher L, et al. Age-related prevalence and twelve-month incidence of illicit drug use in a cohort of Australian gay and bisexual men: Results from the Flux Study. *Drug Alcohol Depend* 2018;188:175-9.
18. Prestage G, Hammoud M, Jin F, Degenhardt L, Bourne A, Maher L. Mental health, drug use and sexual risk behavior among gay and bisexual men? *Int J Drug Policy* 2018;55:169-79.
19. Hammoud M, Vaccher S, Jin F, et al. The new MTV generation: using Methamphetamine, Truvada, and Viagra to enhance sex and stay safe. *Int J Drug Policy* 2018;55:197-204.