



Making Pre-Exposure Prophylaxis (PrEP) Available to People at High Risk of HIV Infection

September 2015

Key Points

1. Pre-exposure prophylaxis (PrEP) is the term used to refer to HIV-negative people taking antiretroviral (ARV) drugs to reduce the risk of acquiring HIV.
2. Efficacy of the ARV drug Truvada as PrEP has been demonstrated in clinical trials among men who have sex with men (MSM), transgender women, heterosexual men and women, and injecting drug users. The UK PROUD study and the French and Canadian IPERGAY study have reported 86% reductions in risk of HIV infection among participants using PrEP to prevent HIV infection. Both these studies were designed to replicate real life circumstances as far as possible and therefore arguably demonstrate effectiveness.
3. Neither the PROUD nor the IPERGAY study found evidence of increased sexual risk taking, allaying concerns that PrEP may lead to risk compensation. These findings were reported at the Conference on Retroviruses and Opportunistic Infections (CROI 2015) in Seattle, in February 2015.
4. AFAO's position –
 - Key actions required to facilitate PrEP uptake are:
 - approval of an application to the Therapeutic Goods Administration (TGA) for a prevention indication for Truvada
 - assessment of cost-effectiveness of subsidising PrEP through the Pharmaceutical Benefits Scheme
 - provision of accurate advice regarding the legal and safe importation of Truvada for PrEP
 - health promotion work to facilitate understanding of the use of PrEP by gay men
 - work with AIDS Councils, NAPWHA and its members to minimise negative attitudes among gay men, clinicians and the broader community, to men who use PrEP as a prevention tool
 - consideration of and communication with other affected communities regarding the role and relevance of PrEP in HIV prevention, in particular for people in serodiscordant relationships.

Background and context

- **Studies:** Efficacy of the anti-HIV drug, Truvada as PrEP has been demonstrated in clinical trials among men who have sex with men (MSM), transgender women, heterosexual men and women, and injecting drug users. These trials have included many thousands of people. The UK PROUD study, and the French and Canadian IPERGAY study, have reported 86% reductions in risk of HIV infection among participants using pre-exposure prophylaxis (PrEP) to prevent HIV infection. Neither study found evidence of increased sexual risk taking, allaying concerns that PrEP may lead to risk compensation. These findings were reported at the Conference on Retroviruses and Opportunistic Infections (CROI 2015) in Seattle, in February 2015.
- **Australian trials:** From mid-2014, PrEP became available in Australia in a limited way through demonstration projects in some states, with Truvada provided to approximately 450 people for a period of one year. These projects are investigating the acceptability, feasibility and impact of providing antiretrovirals for prevention on an ongoing basis.



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- **Regulatory approval:** The manufacturer has submitted an application to the Therapeutic Goods Administration (TGA) for a change in indication, i.e., to allow prescribing of Truvada as pre-exposure prophylaxis. This application is yet to be approved.. Truvada has been approved for use as PrEP in the US since 2012.
- **Cost issues:** Making PrEP available to gay men who are at highest risk of infection would reduce HIV diagnoses in this group and also reduce onward infection to subsequent sexual partners. A recent analysis of a PrEP trial study found that if targeted correctly, provision of PrEP could have a significant impact on the epidemic and be cost effective. PrEP users would not require life-long provision of antiretrovirals. In most cases PrEP would only be used during periods of *increased* risk of HIV infection.
- **Priority actions for Australia:**
 - TGA approval of Truvada for use as PrEP
 - Funding of Truvada as PrEP under appropriate and efficient mechanisms for people at high-risk of HIV infection. These mechanisms may include the PBS. They may also be funded through state health budgets in a similar way that PEP is currently funded.