



HIV SELF-TESTINGⁱ & GAY MEN

Position Statement

ACON is committed to addressing the psychosocial and structural barriers to HIV testing to increase testing rates among gay men.

In particular, we support increasing the range of voluntary HIV testing options within a more accessible service delivery framework.

A significant increase in testing is being asked of gay men through the NSW HIV Strategy yet this is only achievable through the provision of a broad range of testing options that cater for the diverse needs of the community.

ACON believes that existing HIV testing policy and regulatory restrictions on voluntary HIV self-testing (HST), a form of home based testing (HBT), should be removed and greater efforts made to identify opportunities for improving testing service flexibility and consumer choice.

We will continue to advocate that national policies that relate to HIV testing be amended to reflect this position, as well as the need for consumer and practitioner involvement and support.

ACON is committed to working with researchers to better understand how to make the best use of HST in a comprehensive approach to HIV treatment and prevention.

Home based testing raises different issues for gay men and other MSM than it does for other groups, particularly sex workers. This statement covers only the issues that affect gay and other homosexually active men (GHAM) who are not sex workers.

Rationale:

Increasing the proportion of men who test regularly and are aware of their HIV status is critical to ensuring we meet our commitments to reduce infections, in line with the 2011 UN Political Declaration on HIV, and the goals of the NSW HIV Strategy 2012-15.

Research tells us that around 10 – 20% of sexually active GHAM in Australia have never been tested for HIV, with up to a further 25% of these men having no regular testing routine. It is also estimated that up to 20% of HIV positive people may be unaware of their infection. Gay men have identified a number of barriers to testing, including cost and the time spent waiting for results. Reducing and removing these barriers is likely to assist in lowering the threshold to testing access for those who have never tested, while maintaining the primary role of clinical testing. Clinical settings will remain vital in order to perform comprehensive sexual health screens.

Recent data from the NSW Ministry of Health show an overall increase in rates of testing, with increases in the first quarter of 2014 being 9% higher than the first quarter of 2012(4). The 2014 Gay Community Periodic Survey also recorded a 5% increase from 2013 in the proportion of men reporting a HIV test in the previous 12 months. In areas of high HIV prevalence and concentrations of gay men, the annual increase in testing from 2012 to 2013 has been as high as 23%. Of note is the increase that has happened in community run testing sites offering rapid point of care tests. Running since 2013, 8.7% of gay men reported them as being the last place they were tested for HIV despite

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these sites having relatively limited opening hours. This indicates that when given an option that overcomes identified barriers to testing, gay men and other MSM utilise these options.

Australian research has reported that GHAM have a preference for home testing. The CONNECT Study 2012 showed HBT as the most preferred form of HIV testing (5). Research conducted among 2,018 gay men in 2009 also offers clear evidence of a strong preference for home testing, with over 60% of men who have never tested for HIV, one of the most important groups to reach, indicating that they would test more often were they to have access to home based testing (1). These findings are consistent with other Australian and international studies on home based testing amongst gay men and other MSM.

HIV self-testing has been approved for use in similar jurisdictions, including the USA, France and the United Kingdom.

Challenges:

There is limited research into the acceptability and overall experience of HST in Australia at the present time. However, the FORTH study, an RCT examining these very issues is currently being rolled out by the Kirby Institute (UNSW).

ACON is an active partner in this research and is eagerly awaiting the important local findings that are needed for stakeholders to have a more informed understanding of the issue and for the eventual implementation of HST in Australia.

Currently no manufacturer of an HST device has successfully applied to the TGA for listing of a device on the Australian Register of Therapeutic Goods (ARTG), a prerequisite for any device to be sold and marketed in Australia.

The Australian Government must change its regulatory approach to HST so that it ensures the timely assessment of new devices, while guaranteeing the highest quality devices are available for use in Australia.

The National HIV Testing Policy (NHTP) and the slow and costly approval process for listing a device on the ARTG do not facilitate the availability of HST devices.

There are currently several rapid HIV testing devices licensed for use in the USA, including one existing rapid HIV test that has been used in a clinical setting and is now licensed to be used as a home-based test. The test is widely available online and at retail pharmacies. This device is not approved yet in Australia, either at home or for use in a clinical setting.

We acknowledge that access to healthcare, including testing services, is different in the USA when compared to Australia, and that the rate of undiagnosed HIV is significantly higher in the USA. However, we believe home based testing has a role in both settings.

The removal of HST devices from the Therapeutic Goods (Excluded Purposes) Specification 2010, in June 2014, is a welcome first step in removing legal barriers to approval. We also appreciate the provision by the TGA of generic information about HIV self testing on its website.



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However, other barriers remain. The current NHTP has proven to be a significant barrier to regulatory reform as it fails to endorse HST. Although the status of the NHTP in regard to other national policies is unclear, some significant regulatory bodies, such as the TGA, refer to the NHTP and appear to hold the position that the NHTP needs to endorse HST before they can approve devices for listing on the ARTG – currently a condition for use of any screening device in Australia.

We understand that consumers are importing devices via the internet or via overseas travel to jurisdictions that sell HST devices. Due to restrictions contained in section 42DL of the *Therapeutic Goods Act 1989* (TG Act) it would be an offence for individuals or organisations, including ACON, to broadcast information about specific HST devices.

Information such as which testing device is approved for use in other jurisdictions would not be allowed. As such, the current regulatory framework appears to be creating the very conditions that might result in harm, which it purports to avoid.

The introduction of HIV self-testing would require the establishment of pathways to confirmatory testing and linkages to care. This has already been addressed in the USA. It is possible that a proportion of consumers who use HST and get a reactive result may not subsequently engage with appropriate care and support services, but no test can guarantee linkage to care, as evidence of the low but persistent loss to follow up of those tested in care settings testifies.

Local information and education must be provided with HST kits in order to ensure the best outcome for the person testing. The current situation where HST devices are only available via self-importation or online currently does not allow for this information to be provided, thus further reducing the likelihood of access to support and linkage to care.

These issues can be overcome through an appropriately regulated system, which ACON will advocate to see implemented in Australia.



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Endnotes

1 Prestage G, McCann PD, Hurley M, Bradley J, Down I, Brown G, (2010). *Pleasure and Sexual Health: The PASH Study, 2009*. Monograph, National Centre in HIV Epidemiology and Clinical Research, Sydney Australia.

2 Carballo-Diequez, A, Frasca, T et al 'Use of a Rapid HIV Test Prevents HIV Exposure in a High Risk Sample of Men Who Have Sex With Men' *AIDS Behav.* (2012) 16: 1753 - 1760.

3 de Wit, J., Mao, L., Holt, M., & Treloar, C. (Eds.) (2013). *HIV/AIDS, hepatitis and sexually transmissible infections in Australia: Annual report of trends in behaviour 2013* (Monograph 6/2013). Sydney: Centre for Social Research in Health, The University of New South Wales.

4 NSW Ministry of Health (2014). *NSW HIV Strategy 2012-2015: Quarter 1 2014 Data Report*. NSW Ministry of Health, Sydney.

5 Zablotska, I 'The CONNECT Study' *Unpublished presentation* HIV Epidemiology and Prevention Program, Kirby Institute, UNSW. 25 February 2014.

¹ It is important to note that the research cited above asked men about 'Home based Testing', which at the time of the survey was widely understood to mean HIV self-testing. Since that time, the use of dried blood spots collected at home and sent to a laboratory for testing has come to be known as home based testing, and tests administered and assessed by the user have been termed HIV Self-Testing.

Note: This paper contains general commentary and does not constitute medical advice. You should discuss your particular circumstances with your medical practitioner

