

This update has been developed in consultation with our membership as an outcome of AFAO's HIV Self-Testing Forum, held on 23 February 2017. It highlights the national context for HIV self-testing and includes AFAO's views on the optimal model for distribution of HIV self-tests in Australia.

### Policy context

The seventh *National HIV Strategy* sets an ambitious target of virtually eliminating HIV transmission in Australia by 2020. Frequent, easy testing, and early diagnosis are critical if the target is to be achieved. The process of testing creates an opportunity for individuals to know their status and be better informed about HIV prevention including condom use, PrEP, treatment as prevention, the use of sterile injecting equipment and access to opioid substitution.

HIV self-testing is identified in the *National HIV Strategy* as a tool that can simplify the testing process and address access and acceptability issues such as cost, time and convenience. The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine's updated *National HIV Testing Policy* was released in February 2017. The policy endorses HIV self-tests for personal use in Australia, subject to Therapeutic Goods Administration approval of a device.

### Regulatory context and prospects

Until June 2014, regulatory restrictions excluded HIV self-tests from being assessed by the TGA for use in Australia. The TGA's clinical performance requirements and risk mitigation for HIV tests now allow it to assess and evaluate an HIV self-test if an application for approval is submitted by a manufacturer (or a sponsor on a manufacturer's behalf).

At AFAO's *HIV Self-Testing Forum*, Atomo Diagnostics announced that it had applied to the TGA in early 2017 for registration of their HIV self-test device on the Australian Register of Therapeutic Goods.

### Australian evidence

The *Frequency of Oral Rapid Testing at Home* (FORTH) study conducted by the Kirby Institute at the University of NSW assessed the impact of free access to oral-fluid HIV self-testing among gay and bisexual men over 12 months. Study participants had more than five partners or reported condomless anal intercourse in the past three months. Self-testing was assessed overall and among recent testers (tested less than two years ago) and non-recent testers (tested more than two years ago or never tested). The study also looked at the impact of HIV self-testing on the frequency of STI tests among participants and the acceptability of oral-fluid HIV self-testing. The study concluded:

“HIV self-testing resulted in a two-times increase in frequency of testing in gay and bisexual men at high risk of infection, and a nearly four times increase in non-recent testers, compared with standard care, without reducing the frequency of facility-based HIV testing.”

It also found no decline in other STI testing.<sup>1</sup>

## Current access options

In Australia, HIV self-tests can be lawfully purchased online for personal use. As the TGA is yet to approve a HIV self-test for use in Australia, the quality and sensitivity of devices purchased online has not been assessed against Australian standards. Before purchasing an HIV self-test device online, individuals should ensure that the test device:

- has been approved by relevant authorities in comparable countries
- is designed and approved specifically for home use and
- contains instructions for self-testing or home use (rather than instructions for a clinician).

## HIV self-testing in Australia

HIV self-test devices have been approved in the US, UK and France. In these countries, devices can be purchased online through the manufacturer or sponsor's website, through online pharmacies and in-store in pharmacies. There are other models for access and distribution of HIV self-testing, such as via a doctor's prescription or through engagement with health professionals prior to use, although these added steps create additional barriers to access.

HIV self-tests purchased in these countries include online instructional videos for users of the tests in addition to printed instructions in the packaging. Online instructional videos are valuable tools as they enable users of HIV self-tests to emulate the person in the video to support the correct use and interpretation of the test. Online videos can also be translated into other languages for people who do not speak English as a first language or who have low literacy.

To ensure users of HIV self-tests are informed about the test device, information that should be included in the packaging and other consumer information includes:

- the window period for HIV
- the potential for false reactive results (particularly for low prevalence populations)
- the need for confirmatory testing in the event of a reactive result and
- information about how to access support and care.

If self-testing is to increase testing frequency, access needs to be equitable and affordable.

Self-testing should be targeted to populations with a higher prevalence of HIV. In Australia, this population is primarily gay and other men who have sex with men (including trans men). Current data collection relating to people of trans and gender diverse experience is limited. However, in a study of trans and gender diverse people attending Australian sexual health clinics between 2010 and 2016, 5.2% were identified as HIV positive: 8.9% of trans women, 4.5% of trans men and 3.2% of trans patients with no further gender identity information.<sup>2</sup> Trans and gender diverse people could also be considered an appropriate population for HIV self-testing.

Other key populations could consider, and will likely have easy access to, self-testing. HIV self-test devices should be investigated for their effectiveness and acceptability among the communities self-testing is targeted at.

As with all HIV testing in Australia, self-testing should only occur in circumstances where the individual consents to its use.

AFAO would welcome the approval in Australia of HIV self-tests for purchase online through the sponsor or manufacturer's website, through online pharmacies and in-store in pharmacies. We are willing to investigate the additional distribution opportunities of providing access to self-testing devices through AFAO and its member organisations to maximise access to HIV self-testing. In addition to TGA requirements for approval, we would also welcome the availability of additional consumer information such as online instructional videos guiding the correct use and interpretation of the device.

<sup>1</sup> Jamil MS, Prestage G, Fairley CK et al, Effect of availability of HIV self-testing on HIV testing frequency in gay and bisexual men at high risk of infection (FORTH): a waiting-list randomised controlled trial. *Lancet* 2017; February 16.

<sup>2</sup> Callander D, Tsang J, Cook T et al. Blood borne viruses and sexually transmissible infections among transgender men and women attending Australian sexual health clinics. In: 2017 Australasian Sexual Health Conference, 2017 Nov 7-9; Canberra.