



5 May 2014

Professor Chris Baggoley  
Chief Medical Officer  
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Dr Tony Hobbs  
Principal Medical Adviser  
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Dear Professor Baggoley, Dr Hobbs

### **Home testing for HIV**

Thank you for the opportunity to comment on this issue. The comments below are informed by the literature and the expertise of my colleague at CSRH, A/Professor Martin Holt.

1. The risks and benefits of home-testing as a means to enable and promote timely HIV detection and increase testing rates overall, particularly amongst hard-to-reach population groups;

HIV self-testing (HST) is a welcome addition to the range of ways that people can get tested for HIV and ascertain their HIV status. In Australia, surveys of gay and bisexual men, Australia's primary HIV-affected population, indicate strong interest in HIV self-testing, particularly among men who have not sought testing for a long period of time. International research suggests that HIV self-testing can overcome specific barriers to testing, such as discomfort in discussing or revealing one's sexuality, not having a regular doctor and difficulties in accessing health services. The World Health Organization (2013) has issued an initial consensus statement from a range of experts which encourages the uptake of HST as a complementary testing strategy, particularly for priority populations who are recommended to undertake regular and repeat testing. The WHO report does, however, emphasise the need for a regulatory framework to ensure that only quality HST assays are used (to maximise the chance of accurate results), to encourage discussion of how users of HST will be supported and linked to care, if required, and to engage in meaningful community engagement to guide the implementation of HST.

2. The risks and benefits of allowing TGA to approve such devices for HIV self-testing that are of acceptable safety and quality and perform as intended to increase HIV detection rates in Australia;

There appear to be minimal risks to the TGA in adopting an oversight role in ensuring the quality of HST devices that are used in Australia. The TGA has considerable expertise in evaluating the performance of HIV antibody tests against international standards and has recent experience in acknowledging the public health benefits of

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rapid HIV tests (which are generally not as accurate as lab-based assays).

3. Any limitations or conditions that should be placed on the supply of HIV selftesting devices.

Given that Australia has a concentrated HIV epidemic, it may be judicious to limit the use of HST to high-risk populations initially, to reduce the chance of false positives. This will require some creativity in thinking about how to make HST available e.g. through HIV specialist clinicians and HIV community organisations. The availability of HST in Australia will require clear support pathways, such as support and advice telephone lines, which may need to be organised within each state and territory that provides access to HST.

World Health Organization (2013). *Report on the first international symposium on self-testing for HIV: the legal, ethical, gender, human rights and public health implications of HIV self-testing scale-up*. Geneva: WHO.

Yours sincerely,



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