

30 January 2015

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Re: Performance Requirements for HIV Tests

By email: devicereforms@tga.gov.au

Dear Sir/Madam

The Victorian AIDS Council ("VAC") is Australia's oldest AIDS organisation and the leading HIV/AIDS organisation in Victoria.

VAC welcomes this opportunity to work with the government, through the TGA, to provide feedback on the proposed performance requirement for tests to detect the presence of HIV in Australia.

In Victoria, there has been a 32% increase in HIV among gay men over the last four years.¹ In spite of the presence of HIV amongst this population, research shows that gay men and men who have sex with men ("MSM") test for HIV less frequently than recommended in the testing guidelines²

In recognising the importance of testing to addressing the HIV epidemic in Australia the recently launched *Seventh National HIV Strategy 2014 – 2017* includes the following references to testing:

- Improving knowledge among priority populations about the personal and public health benefits of early diagnosis; and
- Supporting high quality, safe, appropriate and accessible testing that facilitates early diagnosis through continued review of regulatory, funding, legislative and policy mechanisms associated with HIV testing.³

These references are replicated in the *2011 United Nations Political Declaration on HIV/AIDS*, of which Australia is a signatory nation.

VAC supports performance requirements, risk mitigation strategies and conditions of approval to enable improved testing infrastructure in Australia including HIV point of care tests ("PoCTs") and HIV self tests. These devices will increase HIV testing in Australia and reduce the undiagnosed prevalence of HIV in Victoria. In saying this, VAC is disappointed that the consultation report overlooks the role of community organisations in responding to HIV in Australia. The report does not acknowledge the existence of community based peer run testing facilities in Australia and, by extension, fails to provide assurances that community based peer testing facilities will survive.

With the support of the Victorian Government, VAC has partnered with the Burnet Institute to establish Australia's first community based HIV testing facility, *PRONTO!*. *PRONTO!* uses trained peer testers (individuals without a tertiary healthcare qualification) to perform HIV point of care tests.

¹ http://kirby.unsw.edu.au/sites/default/files/hiv/resources/HIVASRsuppl2014_online.pdf, page 4

² Spelman T et al, 'Does the frequency of HIV and STI testing among men who have sex with men in primary care adhere with Australian guidelines?' *Sex. Transm. Infect.* 2010; 86(5):3711-376.

³ *Seventh National HIV Strategy 2014 – 2017*, Commonwealth of Australia, 2014



VICTORIAN AIDS COUNCIL

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PRONTO!
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Since the inception of PRONTO! in August 2013, VAC has introduced HIV PoCTs into other non-clinical settings including: social venues, sex on premises venues and festivals. This model has been critical in supporting access to regular testing to target populations where there is a high prevalence of HIV. To date PRONTO! has conducted 2,500 PoCTs and returned 20 reactive results.

Without recognising the importance of the community sector in the response to HIV and HIV testing VAC is concerned that the necessary increases in HIV testing will not materialise.

VAC would welcome the opportunity to provide any additional comments in support of our submission.

Regards



Simon Ruth
CEO

At the outset, VAC believes that all forms of HIV testing should remain voluntary, confidential and be free from legislation or policies that mandate HIV testing in any form.

HIV PoCTs

VAC agrees that rapid HIV PoCTs are an “important strategy to expand access to HIV testing and enable appropriate referral for confirmatory testing and follow up treatment.”

VAC has the following general comments to make about HIV PoCTs in the consultation paper.

- The paper states the following: “Manufacturers are also required to provide studies that demonstrate the performance of the test with serconversion panels and establish the limitations of the test with regard the detection of HIV antibodies (and, if applicable, antigen) in the window period.” Given that HIV rapid tests are measured for their effectiveness outside the window period VAC believes this statement is ambiguous and is need of clarification.
- To ensure that HIV rapid tests are approved as quickly as possible VAC believes that studies showing evidence of performance should include overseas evidence in comparable settings, if the evidence is unavailable from Australian research.

VAC believes that the current conditions around PoCTs are not flexible enough to support peer based testing. Further this consultation paper, disappointingly, fails to acknowledge the important role of non-clinical community based testing facilities in increasing testing amongst target populations. In response to these concerns VAC has the following comments:

HIV PoCTs in community settings

Traditionally, HIV testing has occurred in medical settings. Research shows that many gay men prefer non-medical settings in the context of accessing HIV testing. This is the case because:

- Some individuals do not have regular doctors or are not registered with primary care;
- Some individuals feel stigmatised by attending mainstream medical clinics:
 - for HIV testing; and/or
 - on the grounds that they will be judged because of their sexual orientation or sexual practices.

- of difficulties in finding a gay doctor;
- of the time lag between being tested and receiving the result; and
- The cost of attending medical clinics for testing by healthcare professionals.^{4 5}

To overcome these barriers, and to increase testing rates and HIV detection, community based testing facilities operated by trained and accredited peers have become accepted alternatives to clinical testing settings. These sites are also better equipped to:

- encourage testing amongst high risk individuals who may not otherwise access HIV testing;
- provide non-judgemental easily understood HIV risk reduction information from peers to peers;
- provide peers with referral pathways for counselling, care and support where appropriate; and address the prevalence of undiagnosed HIV in the community.⁶

HIV PoCTs and peer testers

The current regulatory framework is unclear regarding HIV tests being performed by peer testers, who do not have a healthcare qualification. To ensure that peer testers can perform HIV rapid tests, VAC recommends that the TGA amend the wording from 'health professional' to 'appropriately trained and accredited staff' for people who can perform approved HIV PoCTs.

Target populations

VAC recommends that the TGA strengthen HIV testing policy to stipulate HIV rapid tests are most effective when performed on target populations with a high prevalence of HIV, who may not otherwise access HIV testing. In the Victorian context this would involve identifying HIV PoCTs as most appropriate for:

- gay men and MSM;
- recently arrived migrants and their communities from settings with high levels of HIV; and
- at risk Aboriginal and Torres Strait Islander peoples.⁷

⁴ Prestage, G, 'Pleasure and Sexual Health', Sydney, 2009, pp 35-36

⁵ UK National Guidelines for HIV Testing 2008, September 2008, p 14. See <http://www.bhiva.org/documents/guidelines/testing/glineshivtest08.pdf>

⁶ Hickson F, et al, 'Evaluation of the Department of Health funded fasTest HIV testing in the community pilots' London: Sigma Research, 2006. See www.sigmaresearch.org.uk/go.php/projects/project42

⁷ Currently in Melbourne, VAC is involved in a multi-agency initiative to support a cluster of Aboriginal HIV & HCV co-infected peoples. Anecdotally, there are other people who are engaging with this cluster who do not access HIV testing facilities.

VAC believes the TGA should consult with state and territory governments and community agencies to develop guidelines that support the development, and retention, of non-clinical community based peer testing facilities for the purposes of increasing, rather than inhibiting, accessibility to HIV testing. These guidelines should guide the delivery and administration of HIV PoCTs within each of these state and territories. This would include who should operate the testing facilities and which populations should be identified as 'target populations'.

Supervision of HIV PoCTs

There is uncertainty over the term 'supervision' in the paper.

In some community-based settings peers perform tests without a healthcare professional on-site. In these settings a healthcare professional, in the form of a nurse or medical practitioner, provides ongoing monitoring and clinical review to ensure the testing is compliant with current regulations. However, the healthcare professional is not on site at all times. Such arrangements also enable innovative settings for HIV PoCTs to be developed as a way of reaching target populations who may not have sufficient access to testing. Such settings might include event-based pop-up sites at festivals, social venues and sex on premises venues.

VAC recommends that further clarity be provided to support our understanding of 'supervision' in the context of HIV PoCTs.

HIV self-tests

VAC agrees that HIV self-testing is another available option to "improve access to testing and result in increased rates of testing which in turn has the potential to improve the detection of HIV, facilitate earlier access to treatment and reduce transmission rates." VAC recommends that HIV self tests be approved for target populations with a high prevalence of HIV which, in Victoria, includes:

- gay men and MSM;
- recently arrived migrants and their communities from settings with high levels of HIV; and
- Aboriginal and Torres Strait Islander peoples

HIV self testing provides target populations where there is a high prevalence of HIV who, for whatever reason, cannot access existing testing facilities with alternative HIV testing options that offer increased autonomy, privacy and independence. To ensure that the opportunities provided by

HIV self-testing are maximised we recommend augmenting the approval of HIV self testing with the following processes to ensure that the opportunities provided by HIV self testing are maximised.

These processes should include:

- providing information on HIV self testing to ensure the individual is fully informed about:
 - HIV;
 - the self testing device;
 - the limitations of the device; as well as
 - information about other forms of approved HIV testing
- Information should be in plain English and should include access to free foreign language interpretation;
- Information about window periods and the need for repeat testing;
- Information about interpreting results;
- Information advising the user that HIV self tests are a screening device and not a diagnostic device and that any reactive result requires a full blood test;
- Information about HIV and STI risk reduction strategies, safe injecting messages and sites where safe injecting equipment is available;
- Information about re-testing in the event of a negative test result;
- Information about testing for other STIs;
- Information about linking individuals with a reactive result to confirmatory testing services; and
- Information linking individuals who may require further support with options to access services that provide this support. This might include, but not be limited to, after-hours mental health care, LGBTI support and HIV support & counselling.

One of the challenges of HIV self-testing is accessibility to the devices, particularly as self tests are seen as a mechanism to increase testing amongst high prevalence target populations. To overcome problems in accessing HIV self-testing VAC recommends that the TGA consult with state and territory government and affected communities to establish where HIV self testing devices will be available. This should include the locations at which the devices are available including over the counter from pharmacies, clinics, community health centres, community organisations and online purchases by mail or telephone.

To further maximise the opportunities presented by HIV self testing the government could consider providing the information and support for HIV self testing through an online video. This video could

be permanently available and would provide information on use, risks and observing and responding to test results.

Further issues to consider with self testing include:

1. Point of Sale training

VAC recommends that the manufacturer should be responsible for ensuring that there is sufficient training for merchants who are selling or providing HIV self tests to the public. This training however, should not be undertaken by the manufacturer, but should be conducted by government or community agencies.

2. Support for consumers

VAC notes that the TGA recommends that any potential manufacturer may provide online and 24 hour phone line support for users. VAC supports this recommendation but, in so doing, recommends that this service be funded by the manufacturer and conducted by community agencies or the government.