Friday, 30th January 2015

Dr Anthony Hobbs
Principal Medical Advisor
TGA Executive

BY ELECTRONIC SUBMISSION

Re: Consultation on Proposed performance requirement for tests to detect the presence of human immunodeficiency virus (HIV) in Australia

The Australasian Society for HIV Medicine (ASHM) is the peak body of medical practitioners and other health professionals in Australia and New Zealand who work in HIV, viral hepatitis and sexual health.

ASHM works in partnership with stakeholders across Australia to prevent HIV, viral hepatitis and sexually transmissible infections, and to preserve and protect the health and choices of those infected. ASHM achieves these goals through the following:

- Development and delivery of education programs for medical and nursing staff in HIV, viral hepatitis and sexual health
- Prescriber accreditation programs for highly specialized medicines (s100) in HIV, hepatitis B and hepatitis C
- Production of national resources for medical practitioners, health care workers and professionals affected by blood borne viruses
- Contribution to national policy initiatives including State and Federal guidelines, Medicare reimbursement schemes, drug reviews through the Pharmaceutical Board Advisory Committee and advocacy for legislative changes necessary to support the HIV and Viral Hepatitis workforce
- Operation of an International program to provide training, placement, technical and policy advice and clinical resources to increase knowledge about HIV treatment, prevention and care amongst those involved in medical care in the Asia Pacific region

General Comments

ASHM welcomes the TGA review on proposed performance requirements and risk mitigation strategies. The proposed conditions will improve access to testing within target populations by ensuring the availability of a variety of testing options and settings to meet the variable needs of these individuals. Increased testing allows for earlier identification of HIV infection, more immediate linkages to care, reduction in transmission and overall improved outcomes for those infected. In light

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of the expanding landscape of available testing technologies to detect HIV and the settings in which they are designed to be used, it is timely to rethink the performance requirements and risk mitigation strategies appropriate for each.

ASHM feels that the material outlined in the consultation paper is largely reflective of the sentiment in National HIV Testing Policy 2011 and the draft Policy 2013, which is the culmination of the medical, scientific and community views on HIV rapid testing and self-testing. The draft Policy is attached here at Appendix A for your reference.

Performance Requirements

Laboratory testing

ASHM supports the requirements listed in the consultation paper

Point of Care (Rapid Tests)

ASHM prefers use of the phrase 'rapid test' over 'point of care' in line with the draft 2013 National Testing Policy. Generally, 'rapid test' is reflective of the test's use and benefit over traditional laboratory testing while 'point of care' is reflective of where the test may be conducted.

Rapid tests are screening, not diagnosis devices. Because all reactive results must be confirmed with traditional laboratory testing, ASHM agrees with the view in the consultation paper that it is appropriate to have lesser performance requirements for rapid tests as compared to laboratory tests.

To ensure the best performance of a device and the best experience for the user, rapid tests musht only be provided by appropriately trained staff at sites with the necessary quality and governance processes and procedures in place. Guidelines for the use of Rapid Tests are described in the draft National Testing Policy 2013 and are further developed in the NSW Framework and Standard Operating Procedures documents.

One concern which is not mentioned in the paper is the process by which initial performance evaluations are made. ASHM understands that the broader TGA processes are currently under review, however currently the TGA evaluates a dossier as provided by the supplier or manufacturer which is based on a batch or batches of devices. Batch variation has been identified in some of the devices used in research studies. In the consultation paper, there is no mention of:

- the TGA initiating its own testing on devices,
- any post marketing monitoring of test performance, or
- any adverse performance reporting. While this could be incorporated into quality assurance (QA) in respect of PoCT, in the case of self-tests, this would need to be initiated by the individual consumer and thus be included in the package insert.

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While this may be out of scope of this document, the TGA should have the capacity to call for/invite companies to submit devices for evaluation for entry on to the Australian Register of Therapeutic Goods (ARTG) and initiate its own independent reviews, including head to head reviews of devices.

Self-tests

Self-testing is likely to address many of the traditional barriers to testing and increase testing amongst particularly hard to reach populations by allowing individuals to screen when and where is appropriate for them. This will provide the substantial benefit of encouraging testing for those who are most hard to reach and allowing them to conduct their own test in privacy. There are added concerns with these tests however, given the added distance from a health care setting. Because of this distance, it is crucial that appropriate measures are put into place to make sure that individuals can be confident in how to perform the test, what the result is telling them and how to follow up with appropriate medical practitioners.

ASHM supports the reduced performance requirements outlined in the consultation document under the conditions that appropriate support structures and frameworks accompany the distribution of these tests. Such measures should include relevant and clear instructions developed in consultation with community, jurisdictional and clinical partners for users, demonstrations on social media such as you tube for those with low literacy or poor English language skills, clear linkages to care can be outlined in a package insert and ongoing methods for ensuring test performance including clear channels for reporting false results, issues with use or other negative outcomes.

Risk Mitigation Strategies

Laboratory testing

Current risk mitigation practices are acceptable and no further strategies are required.

Point of Care (Rapid Tests)

The single most important risk mitigation strategy is to assure proper training for individuals conducting rapid tests. While there is no need for the individual conducting tests to be a medical practitioners, there is a need for appropriate training which includes test performance and sample collection which is currently provided by manufactures, but also extends to knowing when it is appropriate to recommend a laboratory test above a rapid test (demonstrated seroconversion illness, possible infection within window period), appropriate delivery of results, linkages to care and referral paths that are jurisdictionally relevant. It is not possible or appropriate for device manufacturers to provide these elements of training. ASHM has developed and successfully trailed a Point of Care training curriculum package which has been developed with extensive technical, clinical and community consultation. ASHM recommends that this training package be nationally

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recognized as the appropriate and accredited training for all rapid testing operators as a key risk mitigation strategy.

Along with appropriate training, it is vital to ensure that sites conducting rapid tests have the appropriate quality processes in place, laboratory linkages and governance structures. For the sites to be effective they must be in places that are convenient for the target populations, this has the dual effect of increasing testing and reducing the stigma associated with having a test. Because of their requirement for accessibility and mobility, rapid testing sites cannot be held to the same standard as laboratories, however they must still be able to meet basic quality assurance and control guidelines. It is recommended that TGA indicate that tests should only be delivered in settings which meet best practice guidelines for rapid testing sites as outlined in the National Testing Policy and as drafted in the ASHM Point of Care training materials.

It is important to note that the National Testing Policy indicates that rapid tests are only appropriate for high risk groups in the Australian setting given the low rates amongst the general population. Clarification will be required regarding the suggested requirement that a test be demonstrated in a 'population equivalent to the Australian population' and it is suggested that this be altered in line with the Testing Policy to indicate that rapid tests are appropriate for high risks groups and should therefore be demonstrated within those populations.

Self-test

In order to mitigate risk associated with self-testing, we would recommend some additional processes not yet mentioned in the document, including:

- the provision of reliable, accurate and accessible information on self-testing for HIV with the device, to ensure users understand the purpose and limitations of the devices,
- promotion of local support services to enable linkage to care and support,
- information for users with non-reactive test results and recent or on-going risk of the need to re-test frequently,
- linkage of those with a reactive result to confirmatory testing services, and
- utilisation of surveillance systems to monitor and evaluate the use of HIV self-test.

Conditions of approval

Point of Care (Rapid tests)

Conditions for approval must be clear, concise and must balance the need for safe and effective testing with the benefits derived from having a variety of testing technologies and sites available.

ASHM supports strengthening the requirement to provide sponsor training to include the material outlined as necessary for training under the point of care risk mitigation strategies. To reiterate,

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simple test performance and sample collection is only once piece of what is needed to provide effective rapid tests and these other elements must be taken into account at a policy level.

ASHM supports the delivery of rapid testing sites in innovative ways that best reach target populations so long as the site can meet quality assurance, quality control and staff training guidelines. It is recommended that these clarifications accompany the description of the appropriateness of the setting so as not to limit the types of sites that can be supported.

Self-test

ASHM is supportive of the conditions outlined for self-tests. In addition, a framework developed in consultation with clinicians, community and jurisdictional partners including, but not limited to locations for distribution, communication/education for users, training for clinicians on test availability and performance, packaging, insert information and clear linkages to care should be considered.

Thank you for the opportunity to provide comment on this important and timely issue. Please do not hesitate to contact us should you have any questions regarding our submission.

Yours Sincerely,

[redacted]

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