Queensland
Government

Department of Health

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Dear Dr Hobbs

Thank you for providing an opportunity to offer comment on the Therapeutic Goods Administration (TGA) consultation paper *Proposed performance requirements and risk mitigation strategies for HIV tests (Version 1.0, November 2014)*. As requested, these comments address the performance requirements, risk mitigation strategies and conditions of approval in relation to HIV point of care tests (PoCTs) and HIV self-tests.

HIV PoCTs

Performance requirements

The Department of Health (the Department) largely supports the performance requirements of reduced sensitivity and specificity requirements for HIV PoCT tests in comparison to laboratory tests with the acknowledgement that HIV PoCT is used as a presumptive screening tool. However, manufacturers working with the TGA should strive to improve the sensitivity and specificity of POCTs so that results are more reliable. It is recommended further clarification is provided in the product information that the sensitivity and specificity of HIV PoCT is based on samples tested outside the defined window period to ensure users are fully informed of the tests limitations.

Risk mitigation strategies

The Department largely supports the suggested mitigation strategies for PoCT stated in the consultation paper with the exception of health professional supervision. Further comment with regard to supervision is detailed in the *Conditions of Approval* response below.

Conditions of approval

The Department strongly supports the use of rapid HIV tests in the point-of-care setting to increase access to HIV testing, with the aim of reducing the proportion of undiagnosed HIV infections. Whilst HIV self-testing is an option for people wishing to test for HIV, it is considered preferable for people to test in a supportive environment with access to information.

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Restricting the ability of peer educators to operate more independently could direct people to self-test. The current definition of supervision is too restrictive to be of value for community based services. Research suggests that HIV PoCT and access to testing in non-healthcare settings are often preferred by gay and other men who have sex with men, especially those that engage in unsafe sexual practices (Yang et al., 2014).[1] The current limitation curbs the ability of peer based services, often providing services out of hours or in outreach settings, to offer testing without employing a health care professional to be physically on-site. Allowing for a less restrictive definition of supervision would enable the provision of HIV testing in a greater variety of settings by a greater variety of trained personnel. It appears inconsistent that appropriately trained staff, who have been assessed as competent to perform HIV PoCT to the required standard, are subject to additional conditions from those required of health professionals. A current ethically approved trial in Queensland of HIV PoCT performed by peer educators, supported by the Department, has reported high levels of satisfaction from clients and demonstrated reach to high-risk populations. It is recommended that the definition of supervision be more clearly articulated and extended to include off-site supervision, perhaps with the agreement of supervisor and trained staff member. It is recommended that this change is reflected in the *Product specific conditions* required of sponsors of HIV PoCT by the TGA.

As noted in the consultation paper "*The TGA does not regulate clinical practice*" (page 10), thus it may be inappropriate for the TGA paper to make reference to what constitutes appropriate supervision. Such definitions may be best covered by the National Pathology Accreditation Advisory Committee document *Guidelines for Point of Care Testing.*

The Department supports opportunities for people to access testing in a variety of locations. In reference to location on page 10 of the consultation document "*in an environment where the individual can be provided with appropriate counselling and follow up testing and treatment if required*", more explicit wording is suggested regarding an appropriate location for HIV PoCT. It is recommended that consideration be given to the inclusion of elements of an appropriate testing location that considers the ability to provide adequate infection control measures and a confidential safe quiet space.

HIV Self-Tests

Performance requirements

The Department largely supports the performance requirements of reduced sensitivity and specificity requirements for HIV self-tests in comparison to laboratory tests and HIV PoCT based on user inexperience, with the acknowledgement that HIV self-tests are used as a presumptive screening tool. Outcomes of current studies in Australia using in-home HIV tests, such as the FORTH Study currently conducted by Kirby Institute, could be used to inform appropriate levels of sensitivity or specificity required of HIV self-tests.

Risk mitigation strategies

The Department largely supports the suggested mitigation strategies in the consultation paper. In consideration of the information provided by the sponsor in the Instructions for Use (IFU) or other package inserts, the question of what constitutes a risk for HIV, a clear explanation of the window period and understandable explanations of the sensitivity and specificity of the HIV PoCT are essential.

It is recommended strong emphasis is placed on alternate methods of HIV testing such as PoCT and laboratory based testing for HIV self-test users. HIV testing practices relying solely on HIV self-testing should be discouraged due to the reduced sensitivity and specificity of HIV self-testing. Ongoing assessment of risks and benefits from increased testing with compromised sensitivity and specificity should continue to be monitored by the TGA.

[1] Yang, M, Prestage, G, Maycock, B, et al. 2014 'The acceptability of different HIV testing approaches: cross-sectional study among GMSM in Australia', Sex Transm Infect, 90 (8), pp592-595, retrieved 7 January 2014, < http://sti.bmj.com/content/90/8/592.full.pdf+html>

It is recommended that the wording in the IFU "*the need to consult a medical practitioner for confirmatory testing of positive results by a laboratory test*" is amended to state "the need to consult a medical practitioner for confirmatory testing of reactive results". This acknowledges self-testing is a screening test not a diagnostic test.

Consideration needs to be provided as to the most appropriate contacts for counselling and support services included in the information provided to users, with respect to different jurisdictions. A person with newly diagnosed HIV infection may be deterred from engaging in care if the services they contact are unable to provide immediate support. In addition, it is recommended it is stated that if the person testing is still concerned with regard to risks or symptoms, even if the result is non-reactive, they should seek medical advice.

Conditions of approval

The Department largely supports the proposed conditions of approval for HIV self-tests. The Commonwealth and jurisdictions could work together in considering alternative support mechanisms. Consideration should be given to alternative methods of support that could be provided to users other than online / 24 hour phone line provided by sponsors. The financial investment in support services for sponsors may act as a deterrent to apply for approval in Australia. Alternative support could include the use of existing 24 hour telephone services such as the Queensland Health 13 HEALTH telephone advice line for Queensland users of self-tests or support training for pharmacists selling HIV home testing kits. Additional consideration could be given to organisations with trained peer educators acting as a point of sale for HIV self-tests.

I thank you once again for the opportunity to provide comment on the consultation paper. Please contact [redacted], Communicable Diseases Unit, on [redacted] or email [redacted] if you require further information.

Yours sincerely

[redacted]

Dr Jeannette Young
Chief Health Officer
30 / 01 / 2015