Queensland
Government

Department of Health

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Professor Chris Baggoley and Dr Tony Hobbs
c/o Ms Lisa Studdert
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Dear Professor Baggoley and Dr Hobbs

Thank you for the opportunity to comment on the proposal to allow the registration and sale of invitro diagnostic devices (IVDs) for self-testing (home testing) for the presence of human immunodeficiency virus (HIV) in Australia.

The Queensland Department of Health's (DoH) Communicable Diseases Unit supports the investigation of new technologies that will allow timely diagnosis of people exposed to HIV and their subsequent engagement and retention in treatment and care. This proposal supports the outcomes of the *Queensland HIV Strategy 2013-2015* to increase voluntary testing for HIV. However, the Immunology Section of Pathology Queensland, Queensland Health, has voiced concerns regarding the low sensitivity of the IVDs used for self-testing (home testing).

Please find enclosed a table outlining specific comment on the areas you requested.

I would welcome future opportunities for the Queensland Department of Health to discuss or comment on the proposal. Please contact [redacted] Communicable Diseases Unit, [redacted] if you require further information.

Yours sincerely

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5/5/14

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Therapeutic Goods Administration (TGA) proposal to allow registration and sale of IVDs for HIV home testing

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

Risks

- 'Window period' is problematic and if people are not fully cognisant of the limitations of the test and the timing when the test is performed, then we could see a strong reliance on the test for "morning after" testing or without adequate follow up, which is not advisable. People may not measure the window period accurately, particularly if they have had multiple potential exposures.
- People may use the test for wrong purpose: e.g. as a risk reduction strategy to determine their status prior to engaging in risky behaviour (in individual and group instances and potentially at private residences for sex parties).
- Ensuring that people who take a home HIV test, and who test positive, have a confirmatory test, are able to access support and are engaged in treatment and care as required.

Benefits

- Increase access for hard to reach populations – this is of particular significance for Queensland with the population spread across a wide area, including rural and remote towns
- People who may not wish to access mainstream services will be more likely to conduct a test using home testing
- With support, the CALD population may use the test more readily
- Encourages testing as a routine exercise the individual can take on as part of their health care regime
- Increases knowledge and understanding of HIV transmission, amongst the population (which could occur through test kit information sheets, advice by pharmacists, 1800 helpline, healthdirect Australia or peer discussions, etc.).
- The level of knowledge about HIV by some men who have sex with men is already high.

Comments

- The US experience can provide us with clear guidance as to any limitations to home testing and benefits of the two FDA approved tests used.
- It should be feasible to put in place some supports for a home based HIV testing system (written and verbal) if we currently have a widespread system of home pregnancy tests purchased at a supermarket or pharmacy and providing a life changing (and potentially life shattering) event, often with no support.

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

Risks

- The home tests do not provide a confirmatory result, leaving a risk for false negative or positive results.
- A false negative result may see people engaging in risky behaviour thinking they are HIV negative, when in fact they may be positive.
- The US experience through FDA approved products is only through the OraQuick or HIV-1 Test System.
- The UK are yet to approve any devices for HIV home testing.
- Some people who test positive may choose not to get confirmatory testing or treatment.

Benefits

- Ease of access to the test and its use should encourage testing by the individual.
- Home based testing provides an additional means for engaging clients in regular and ongoing testing.
- Making testing easier (depending on the test and instructions etc) and allowing testing in the privacy of a person's home, should encourage testing.
- Increased testing should reduce the pool of infection and result in declining rates of HIV if people choose new behaviour after diagnosis.
- The TGA will be able to provide appropriate conditions on sale and use of the test to ensure effective testing and allow for follow up.

Comments

- Pharmacists and pharmacy assistants could be trained in use of the test (including some pre and post-test discussion).
- A 1800 helpline should minimise problems and assist with the effective implementation of the test, queries by customers, access to counselling etc. This telephone line could potentially be linked to existing information lines operated through Commonwealth and State governments; and community based organisations.
- A phased roll out would be ideal, offering the opportunity to evaluate the test. Evaluation could include: demographics, ease/problems with use, number and type of calls to helpline, number of positive/negative results etc.
- Perhaps the home sampling kit (HIV-1 Test System) could be made available through pharmacies (and their online stores) for the general population as it provides an opportunity to engage the person in counselling and care; and the OraQuick test used for high HIV prevalence populations such as MSM.

3: Any limitations or conditions that should be placed on the supply of HIV self-testing devices

Comment

- Suggest to limit supply to say 3 tests per customer, 16 years of age and over.
- Provide clear guidance from pharmacists/pharmacy assistants or online, if requested, when tests are purchased to ensure consumer is aware how to operate the device.
- Provision of information resources with tests, including a 1800 24/7 number for advice and counselling.
- Potentially incorporate a service were people could take a photo of their test strip and send the result to a central office where the result could be confirmed and advice given over the phone.
- A system to collect data on home testing to evaluate the program.
- Provision of training to health service providers on these tests and counselling.