6 May 2014

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SCIENTIA PROFESSOR & DIRECTOR

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Dear Professor Baggoley and Dr Hobbs

Thank you for your letter of 15 April 2014 inviting views on the risks and benefits of home-testing in relation to a proposal under consideration by the Therapeutic Goods Administration (TGA) to allow the registration and sale of in-vitro diagnostic devices (IVDs) for self-testing (home testing) for the presence of human immunodeficiency virus (HIV) in Australia.

We provide this commentary in the format of a letter plus a fully referenced appendix.

The Kirby Institute at UNSW is Australia's leading clinical and epidemiological research centre in HIV, and manages national HIV surveillance. Researchers at the Kirby Institute have undertaken considerable research on HIV testing, and specifically home-testing, that can inform the current considerations by the TGA. The Kirby Institute has recently commenced a randomised controlled trial of home HIV testing among gay and bisexual men, however as this study has only recently commenced no results are available. This trial will compare HIV testing frequency among men who have access to home based HIV testing compared to clinic-based testing.

HIV testing is a key public health strategy to control the HIV epidemic. Increased HIV testing should lead to earlier detection of HIV infections. This allows a reduction of transmission to others by the person being aware of their HIV status and modifying risk practices, or by initiating treatment which can suppress viral replication and thereby reduce infectiousness. In Australia, HIV testing rates are less than ideal.

In regards to the benefits, home-testing is likely to provide a means for people at high risk of HIV to test more frequently. Increased HIV testing, leading to earlier diagnosis of HIV infection has become a much more important preventive strategy recently, in the new biomedical HIV prevention environment. HIV diagnoses are concentrated in gay and bisexual men, but there are also high rates in people from Sub-Saharan Africa and Asia living in Australia. The annual number of HIV diagnoses has increased by 43% in the past ten years, from 876 diagnoses in 2003 to 1253 in 2012. Over that period there has been no major change in self-reported annual HIV testing rates in the highest risk population, gay and bisexual men.

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The current time from infection to diagnosis has been estimated to be about 4 years on average. Less than a quarter of high-risk gay and bisexual men are testing at the recommended frequency (which is 3-6 monthly for most sexually active gay men) and there are still around 14% of gay and bisexual men who have never tested. Among people from Sub-Saharan Africa and Asia about 50% report that they have never been tested. Almost 40% of all new HIV diagnoses in Australia have CD4 counts below 350 cells/mm, suggesting they were infected many years earlier. Being diagnosed late with HIV results in reduced life expectancy, increased HIV-related morbidity, and increased costs to the health system.

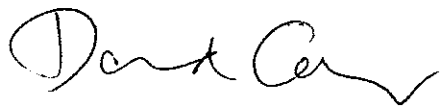
Surveys of gay and bisexual men consistently show that they report a range of structural barriers to HIV testing and easy, more accessible options would increase testing rates. Around 50-70% of men report they would test more frequently if home-testing options were available.

The main risk of the OraSure OraQuick home-test, which is licensed for home sales in the USA, is that the sensitivity is lower than laboratory-based tests. False negatives are particularly likely to occur in the few weeks after HIV infection is acquired. However we calculated that if high risk men tested more frequently (>40% more, or from 2 to 2.8 tests per year) because they had access to home-tests, which seems plausible considering the interest from self-reported surveys, then any additional loss in test sensitivity would be offset at the population level by additional infections detected. Also home-testing would have a public health benefit if untested gay men or other populations at risk, simply had a HIV test that they would otherwise not have had. In its assessment of an application from OraSure for home sales of its OraQuick oral rapid HIV test, the US Food and Drug Administration considered that the potential benefit of home testing in increasing detection of HIV among people with undiagnosed HIV infection outweighed the risk of false negative tests.

Poor technique among those using home HIV tests (and the risk of false negatives because of it) has been raised as a concern by some, but studies have shown that home users can perform the test accurately without training when the information provided with the kit is clear. Another concern raised is that those who receive a reactive result on a home test would not refer themselves to care after a reactive result. There is no evidence to support such a scenario, and even if it did occur a person being aware of their HIV status through a home test is preferable to not knowing at all. A further concern raised is a person having an adverse emotional reaction in response to receive a receiving a result in their home. However we also do not believe there is any evidence to support this occurring, and Australia has numerous HIV support phone lines that could be accessed if needed.

Overall, we believe that the availability of home HIV testing would be a net benefit in increasing testing rates in Australia and detection of HIV. Risks can be reduced by requiring clear information and labelling, including advice to seek comprehensive HIV and STIs testing at clinics in addition to using a home test. Risks that may result from home testing need to be considered in the context of the ongoing harms from increasing incidence of HIV and the continuing high rate of late HIV diagnoses in Australia.

Yours sincerely



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Appendix: HIV surveillance and research data relevant to home HIV testing.

1) HIV Testing rates among populations at increased risk of HIV infection

Data from behavioural surveys of populations at increased risk of HIV infection suggest that increased uptake of HIV testing, and more frequent re-testing is needed to achieve a public health benefit in increased detection of HIV and a reduction in new HIV transmissions:

- The proportion of gay and bisexual men who report ever having tested for HIV has fallen slightly in recent years. In 2012, 86.4% of men surveyed in the Gay Community Periodic Surveys reported that they have had at least one HIV test. [1]
- The proportion of gay and bisexual men who report having tested for HIV in the last 12 months has been stable in recent years at around 60% among all men but has recently fallen among men aged under 25 years (62% in 2003 to 59% in 2012). [1]
- Less than a quarter of high risk gay and bisexual men (men who have high numbers of casual partners and/or unprotected anal intercourse) re-test for HIV at the frequency recommended in HIV testing guidelines. [2, 3]
- In surveys of gay and bisexual men where recruitment is conducted online, leading to a higher proportion of non community-attached gay and bisexual men, a higher proportion of men report never having tested for HIV. In the 2008 E-male survey, 23.8% of men reported that they had never tested for HIV. [4]
- Among Australian people from countries in Sub-Saharan Africa and Asia with high HIV prevalence, only 50.3% report having ever tested for HIV. [5]

2) Previous HIV testing among people diagnosed with HIV and late HIV diagnoses

HIV surveillance data suggest that more timely HIV diagnosis is needed. People who remain undiagnosed for long periods are at greater risk of HIV-related mortality and morbidity, and may be unwittingly transmitting HIV to others.

- Fewer than 40% of gay and bisexual men newly diagnosed with HIV had tested for HIV in the 12 months before diagnosis [6]
- The estimated median period between HIV infection and HIV diagnosis is approximately 4 years [7]
- Between 2008 and 2012, 39.3% of HIV diagnoses in Australia were late diagnoses (<350CD4+ cells/μl) [6]. People diagnosed late are at increased risk of HIV-related mortality and morbidity. [8]

3) Preference for home HIV testing among gay and bisexual men

Behavioural surveys of gay and bisexual men in Australia consistently show that a high proportion of men would indicate they would test more frequently if they had access to home HIV tests.

- TAXI-KAB Survey 2012 (*n*=567)
    i. 36.5% said they would be 'likely' and 34.3% 'very likely' to use home self-testing for HIV if it was available in Australia
    ii. 47.6% indicated that having the capacity to test themselves at home would likely increase their willingness to test and to test more often
    iii. Men who engaged in unprotected anal intercourse with casual partners, who were not gay identified and who indicated inconvenience issues with using clinic-based HIV testing were more likely to indicate a willingness to use home tests [9]

- PASH Survey 2009 (n=2,018)
    iv. 67.4% indicated that they would test more frequently if they could test themselves at home
    v. In a multivariate analysis of responses from untested men, factors independently associated with indicating an increased frequency of testing with home testing included:
        a. Stating a preference for not needing a doctor's consultation when testing (AOR 3.54; CI 1.90-6.62; p<0.001) [10]

4) Increased HIV testing uptake and home HIV test sensitivity

The Kirby Institute recently completed work to estimate what frequency of HIV testing among GBM would be required to outweigh the lower sensitivity of home HIV testing. [11] This analysis, undertaken by Associate Professor Rebecca Guy, Associate Professor David Wilson and others at the Kirby Institute found that:

- If high risk GBM undertook a home self-test instead of a laboratory test (a 4th generation EIA), 6.55% of infections that would have been diagnosed with laboratory testing would not have been detected with the home test. This proportion would fall to 0.44% if two home self-tests were undertaken in a year
- If use of home self-tests resulted in a 40% increase in HIV testing frequency among high-risk GBM (2 to 2.8 tests per year), then an equivalent number of infections to the current situation would be detected.
- If the increase in testing was greater than 40% or men who had never previously tested undertook at least one HIV self-test, then additional infections would be detected and there would be a net benefit. [12]

5) Home testing and clinic-based HIV testing

In a qualitative study of attitudes to self-testing among gay and bisexual men by the Melbourne Sexual Health Centre, men reported that they would supplement clinic-based testing with home testing between clinic visits. [13]

6) Linkage to care among people who receive a reactive home HIV test result

Studies of home HIV testing have shown that self-referral to medical care is high among people who receive a reactive home HIV test result.

- Among people who received positive diagnoses in the U.S OraSure home use study, 96% had indicated before testing that they would seek care if they received a reactive home test result. [14]
- In a study of home testing study in the Kwa-Zulu Natal province of South Africa, 90% of people diagnosed positive had visited a clinic within three months. [15]

7) Acceptability of HIV self testing

- A recent systematic review of studies of supervised and unsupervised HIV self testing identified 21 studies of self testing in high and low risk populations; HIV self testing was found to be highly acceptable (74%-96%), and preferred to clinic based testing (79%-81%). [16]

8) Safety of HIV self testing

Two systematic reviews published in 2013 did not find any evidence of suicide or increased self-harm among participants in studies of HIV self testing. [16-17]

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