

Department of Health and Human Services

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Professor Chris Baggoley (Chief Medical Officer)

and Dr Tony Hobbs (Principal Medical Adviser)

Department of Health

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Chris & Tony
Dear Professor Baggoley and Dr Hobbs

Subject: Proposal for the registration and sale of in vitro diagnostic devices (IVDs) for self/home HIV testing

Thank you for your letter of 15 April 2014, seeking the view of the Tasmanian Department of Health and Human Services regarding a proposal 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 have consulted with our Sexual Health Service colleagues in responding to your questions. Dr Scott McKeown (Tasmanian representative on Blood Borne Viruses and Sexually Transmissible Infection Subcommittee) and Dr Mark Veitch (Tasmanian representative on Communicable Disease Network Australia) also received letters; this response incorporates their views.

We support considered efforts to improve accessibility, acceptability and timeliness of HIV testing in at risk populations that are under-tested. Identifying HIV infection earlier by any means enables infected persons to receive early care, treatment and advice. This is expected to achieve clinical and public health benefits. Existing and new strategies including rapid HIV point-of-care testing in outreach settings are currently undergoing field evaluation.

An important aim of making safe, good quality and well-performing HIV self-testing kits available in Australia is to increase the diagnosis of undiagnosed HIV infection and in particular the diagnosis of recently acquired HIV infection.

To achieve this clearly beneficial objective, HIV self-testing needs to be taken up by persons at risk of having or acquiring HIV infection, and particularly by those persons who would not otherwise have sought timely testing though either conventional or point-of-care testing.

A process that ensures that HIV self-testing kits available in Australia are safe, of good quality and perform well is desirable, and helps mitigate some of the risk associated with unregulated private importation of such products.

HIV self-testing would add a new element to an already rapidly evolving HIV testing and care environment. It would therefore be important to evaluate the contribution of HIV self-testing to diagnosis, early diagnosis, and early initiation of treatment for HIV infection, within this dynamic milieu. This includes consideration of potential public health benefits and risks, and measures to mitigate these risks. Assessment

should also include the relative cost-effectiveness of HIV home-testing and the impact on the healthcare system of increased HIV diagnoses.

HIV self-testing without pre-test and post-test counselling may result in risks and even harm to the tested person and public health. A person with a positive HIV self-test still needs to take the extra step to engage with clinical services for confirmatory tests, assessment and appropriate care, contact tracing, and advice to reduce further transmissions. A person with a negative HIV self-test may take inappropriate reassurance about risky behaviour. A person with a potentially false-negative HIV self-test may also be inappropriately reassured about their HIV status if the test was performed during the window period after an exposure. A false positive HIV self-test may be taken as a definitive and distressing diagnosis by an insufficiently informed person.

Some of these risks associated with HIV self-testing could be mitigated by requiring information to be provided at the point of supply explaining the significance of test result including considerations of the 'window period', at-risk behaviour, and the clinical follow-up of positive results. Supply could be restricted to points at which this information could be provided e.g. pharmacists, or clinicians (for example a "take away" test for use in the interval between clinically supervised tests). There may be challenges in requiring this information to be provided for internet-based supply of IVDs for HIV home-testing.

The ethical and legal ramifications of readily available HIV self-testing need to be explored. These include the potential for such tests to be used for non-clinical purposes, such as in insurance, occupational or other contexts. The prospect of surreptitious use to test an unsuspecting, uninformed and non-consenting person also arises, particularly for saliva-based tests.

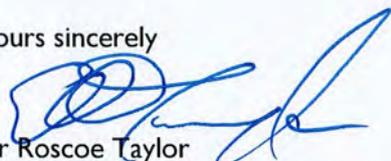
Managing persons who put others at risk of HIV infection depends on such persons being aware of their positive HIV status. This awareness has, to date, been based on information from conventional HIV tests; with the communication of the result done and documented by a clinician, and a process established to manage this risk. The obligations of a person with a positive HIV self-test not to put others at risk of HIV infection need to be articulated.

We need to consider the consequences of readily available HIV self-testing for the good clinical management of persons at risk of sexually transmissible infections (STI). For example, might HIV self-testing reduce testing and management of other STI?

HIV self-testing may have consequences for public health surveillance of HIV infection, including recently acquired HIV infection. A process to facilitate confirmatory testing for HIV in conventional settings needs to be linked to HIV self-testing to maintain both surveillance and routine public health responses to newly diagnosed HIV infection. A related issue is the need to establish ongoing surveillance of HIV self-test use, to monitor the performance of HIV self-test kits, and to have product warning and recall mechanisms.

The recent experience of the United States and United Kingdom will be useful to consider, to understand the value and pitfalls of HIV self-testing, but with an Australian perspective in mind. The overall usefulness of HIV self-testing will ultimately depend upon the extent to which it can meet needs that are not currently met by existing testing, and the associated public health risks can be mitigated.

Yours sincerely



Dr Roscoe Taylor

Chief Health Officer/Director of Public Health

6th May 2014