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Editorial
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Time to roll out rapid testing for HIV? Yes, but with appropriate safeguards

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In a study published in this edition of *Sexual Health*, Wilson *et al.* using mathematical modelling, suggest that individuals with primary HIV infection and those who are HIV infected but undiagnosed, contribute disproportionately to new HIV infections among men who have sex with men.[1] Based on these findings, they make the case for increased HIV testing to increase rates of HIV diagnosis.

The diagnosis of HIV has clear benefits for HIV infected individuals as well as the population. For the individual, early diagnosis provides the opportunity for appropriate patient management and initiation of antiretroviral therapy at an optimal point in time, which can now offer the expectation of a near normal life span.[2] In contrast, those who are diagnosed late have much poorer health outcomes at significant health service cost. It is a disheartening reflection of current testing strategies that a substantial proportion of people newly diagnosed with HIV still present at an advanced stage in their infection.[3] In the UK, 31% of people newly diagnosed with HIV first present for testing when their CD4 count is less than 200.[4] At the population level, early detection of HIV contributes to improved HIV control by enabling partner notification and evidence suggests that individuals diagnosed with HIV usually alter their sexual behaviour so as to reduce the risk of further HIV transmission.[5]

The benefits from increased HIV detection would be greatest in populations where the proportion of undiagnosed individuals is highest. In 2003, there were an estimated 1 million persons infected with HIV in the USA with one-quarter of these persons unaware of their status.[6] In the UK it is estimated that of the 77 400 people with HIV, 28% of them are unaware of their infection.[4] These data highlight a pressing need for new approaches to reduce barriers to testing.

So how might testing for HIV be substantially increased? One way is through the use of rapid testing for HIV using either a finger prick blood sample or a sample of oral fluid obtained by a mouth swab with results available at the point of testing within minutes.

The use of rapid HIV testing confers a number of potential benefits which may reduce barriers to testing. Rapid testing removes the typical 1–2 week delay between test and result with conventional HIV blood tests. This is important as it is not uncommon for clients to express anxiety about this waiting period and this may actually deter individuals from testing.[7] Recent studies suggest that clients favour rapid HIV testing over conventional testing, citing the immediacy of results as the main factor behind this preference.[8–10] The provision of a result at the time of testing has the added advantage of preventing loss of patients to follow up. In the USA, 31% of people who tested HIV positive in 2000 did not return for their test result.[11] However, the implementation of rapid testing in New York State in 2003 meant that 100% of those tested received their result and led to a 36% increase in testing over the previous year resulting in increased detection of previously undiagnosed HIV.[8]

A further advantage of rapid HIV tests is that they are ideally suited to non-clinical or community settings, providing access to HIV testing to individuals who might not otherwise access clinical services for testing. Oral fluid sampling may confer added benefits to users over finger prick blood testing as it may be perceived as less invasive and is less painful. Given that oral fluid is not considered potentially infectious unless it contains blood, the disposal of samples is also much easier.[12] Many settings have been proposed as outreach sites including bars, clubs and saunas, further education and sports settings. However, we must recognise that individuals need a choice of venues for testing to include both community and clinic-based settings, as people vary greatly in their preferences. One sauna based UK study of men who have sex with men reported that some men would not feel comfortable testing for HIV in a club as they feared the consequences of receiving a positive result in that setting.[13]

Rapid testing appears popular with health care professionals.[14] Moreover, after training and experience with rapid testing, counsellors without previous laboratory training have shown proficiency in rapid testing and express a preference for rapid testing over conventional testing.[8,15]

A number of rapid HIV tests have been approved for use by the US Food and Drug Administration (US FDA).[16] Some of these have only been approved for use within the laboratory setting, whereas others can be administered outside laboratories by persons without formal laboratory training.[17] The OraQuick *ADVANCE* Rapid HIV-1/2 Antibody Test (OraSure Technologies, Bethlehem, PA, USA) stands out as it can provide

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results in 20 min using oral fluid, avoiding the need for either the fingerprick or venipuncture that is required for other rapid HIV tests to be performed. The OraQuick *ADVANCE* rapid HIV test has received a Conformité Européene (CE) mark which is required for marketing within the EU and is licensed for use in the UK.[12]

There are a number of potential limitations with the use of rapid HIV testing. As with HIV enzyme immunoassays, a window period applies and there have been reports of false-positive results.[18,19] In general, however, the performance of the FDA approved rapid HIV tests is similar to that of HIV enzyme immunoassay tests. In the case of the OraQuick *ADVANCE* Rapid HIV test, both the sensitivity and the specificity are in excess of 99%.[20] Reactive rapid test results need to be confirmed using supplementary testing such as Western blot. Ideally, confirmatory testing should be offered at the point where a provisionally reactive rapid test result is received to ensure confirmation is undertaken.[17] Any programs utilising rapid HIV testing also need adequate quality controls to be in place and provider training for accurate interpretation of results.[12,17–19]

The ease of use of the rapid HIV testing technologies now means that it is now possible to self-test for HIV using a home test kit and some internet medical service providers in the UK already offer this. Considerable debate has arisen over whether home testing for HIV should be available. Some have argued that home testing could provide increased access to HIV testing together with the anonymity and privacy that many individuals seek.[21] Others have voiced concerns about the potential downsides of testing in the absence of direct contact with a health provider. Testing under such circumstances might limit the opportunity for counselling aimed at risk reduction or the support and health advice that should be offered in the event of a positive result. However, these concerns need to be balanced with the right of individuals to make their own choices and the potential benefits to the community from reduced HIV transmission. Indeed, there has been strong support for home HIV testing from some quarters.[21]

The only US FDA approved home test for HIV is the Home Access Express HIV-1 Test System (Home Access Health Corporation, IL, USA) which requires a self-administered fingerprick and production of a dried blood spot. It is not a rapid test and must be mailed to a laboratory for testing.[16] To access results, users of this kit are asked to call a toll free telephone number with a personal identification number. Information that would normally be provided as part of pre- and post-test counselling is provided using printed material and over the telephone.[16] The OraQuick *ADVANCE* rapid HIV test has not been approved by the FDA for home or self-testing; however, Orasure Technologies are seeking approval for it to be available over the counter.[21]

With advances in technology and drive from commercial interests it is inevitable that more rapid tests and home testing systems for HIV will emerge. Home HIV tests have been marketed through the internet and media, in some cases involving tests that have not been FDA approved, raising the spectre of public access to tests of dubious quality.[16] The challenge for health and regulatory authorities will be to ensure adequate regulation of such practices. The availability of approved, quality assured home tests for HIV may be one way of undermining trade in fraudulent or illegal tests.

Further studies should examine the possible benefits and safety of different models for increasing access to HIV testing in different populations and groups at risk. Such efforts should take into account the needs and sentiments of individuals and the public. We believe that introduction of rapid HIV testing in Australia, with appropriate quality assurance, regulation and monitoring will be a key step in removing some of the well recognised barriers to HIV testing, and that has to be a good thing.

Conflict of interest

Claudia Estcourt has undertaken studies to evaluate new testing technologies for HIV.

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