

HIV self-testing: a time to revise current policy

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A review of government policy about self-testing for HIV is needed in the UK. Since 1992 to sell or otherwise provide a member of the public with any form of self-test for HIV has been illegal in that country.¹ This policy, which was developed at a time when HIV was regarded as different from other diseases (ie, exceptionalism) in public health measures,^{2,3} is now outdated. New technologies that enable rapid and accurate HIV testing are now becoming available.⁴ To increase the uptake of HIV testing and truly respect patient autonomy we need to challenge this outmoded practice and remove the legal obstacles to self-testing for HIV.

On Nov 3, 2005, the US Food and Drug Administration's (FDA) blood products advisory committee met to debate the issues raised by a self-test for HIV based on oral fluids, after its manufacturers declared their intention to seek over-the-counter status.⁵ The committee's meeting is the first stage in a long approval process, but it suggests that self-testing for HIV is being considered in the USA. Most of the experts who spoke at the meeting argued that the introduction of self-testing for HIV was long overdue.⁶

Self-tests for HIV need to be distinguished from home-sample-collection test kits. With these tests, the patient takes his or her own blood sample at home, then sends it to a laboratory for testing and receives the results by telephone. Such tests have had FDA approval since 1996.⁷ With self-testing for HIV all stages of the test would take place in the patient's home, in the same way as a home pregnancy test. The patient would obtain the sample, such as an oral-fluid swab, and the result develops in about 20 min. If the UK were also to legalise HIV self-testing, there are good grounds to believe that legalisation would increase the uptake of HIV testing—a major UK government health target.⁸

An estimated 31% of people with HIV in the UK are unaware of their HIV status, and with advances in highly active antiretroviral therapy the patient should be diagnosed quickly so that the illness can be managed effectively.⁹ Early diagnosis also has public-health benefits because people who are HIV positive and are aware of their status are more likely to change their behaviour to reduce the risk of transmitting HIV to others.¹⁰ Self-HIV testing has been suggested as one means of increasing the uptake of HIV tests.^{4,11}

Preliminary investigations in the USA suggest that there is a demand for self-testing. Some sectors of the population would find self-testing more satisfactory than HIV testing in a medical setting¹¹ and for others it would be more satisfactory than testing of samples taken at home.¹² Whether self-tests result in an overall increase in HIV testing in the UK would have to be monitored, but results from studies in the USA are encouraging. Along with a probable increase in overall uptake, self-testing would

enhance patients' choice. People would have more say over where, how, and when they would be tested for HIV. This promotion of patient autonomy is central to the case for self-testing.

There is a trend in health care towards an emphasis on patient autonomy, which has led to greater self-diagnosis and screening. People are encouraged to take responsibility for their own health, with the recognition that they can make informed decisions without direct intervention from health-care professionals. The restriction of HIV testing to clinical settings is unwarranted, because it prevents individuals from fully exercising their autonomy. As an editorial in the *Canadian Medical Association Journal* said, "Where the technology exists, why should the public not have autonomy and privacy in obtaining important health information [on their HIV status]?"¹³

Since patient autonomy is important in current medical practice, there should be good and weighty reasons to justify restriction of that autonomy. If self-testing for HIV could be harmful in some way, there would be grounds for keeping HIV testing in a clinical setting. However, none of the arguments put forward to justify the harmfulness of self-testing are strong enough to merit the continued illegality of such tests.

The most common argument used against self-tests is that the person would not receive face-to-face counselling before or after the test.^{5,14} Mandatory pretest face-to-face counselling in HIV is a legacy of exceptionalism: something that is increasingly questioned.^{2,3} Although such counselling can be beneficial, for some people a requirement for pretest face-to-face counselling can actually deter them from being tested.^{12,14}

The argument about the absence of pretest counselling with self-testing needs to be considered in the context of the general re-evaluation of the role of HIV counselling.^{9,15} In practice, the way HIV testing and counselling are done is beginning to change. In response to calls to increase the numbers tested and reduce waiting times,⁸ the British Association of Sexual Health and HIV draft guidelines suggest that genitourinary medicine clinics should stop routine pretest counselling. Before undertaking the test patients are recommended to have a pretest discussion, the primary objective of which is to ensure informed consent for the test. Traditional counselling should be reserved for those making a specific request and those who are at high risk of a positive result.⁹

The most radical change in HIV testing and counselling is perhaps universal antenatal testing for HIV. All pregnant women in the UK are routinely asked to give their consent to an HIV test, but most will not receive counselling. Guidelines issued by the UK General Medical Council state that counselling needs to be available only for women assessed as at medium or high risk of HIV infection.¹⁶ In

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view of the changes in genitourinary clinics and the universal antenatal HIV testing, the opposition to self-testing on the grounds that there is no pretest face-to-face counselling is severely undermined.

Although practice in pretest counselling is changing, the predicted lack of counselling after a self-test is the most serious concern.^{4,17} Many health professionals have argued that people receiving a positive HIV test result on their own would suffer greater distress and anxiety than those receiving their results in a health-care setting.¹⁴ However, self-testing does not necessarily mean there would be no counselling or support. Although there would be no face-to-face counselling, telephone counselling would have to be available. In the UK, the Parliamentary Office of Science and Technology has argued that there should be a requirement on the manufacturers of any self-test to provide some form of counselling as part of their testing service.¹⁸ Fears about the lack of face-to-face counselling were raised when the US FDA was considering home-sample-collection HIV tests in the early 1990s,⁶ but studies on the implementation of these tests, for which telephone counselling was available, did not show any adverse consequences such as increased suicides associated with their introduction.¹⁹

Counselling would also be available when people sought a confirmatory test. As with any HIV test, a second test in a health-care setting would be needed to confirm positive results of a self-test. Information directing people to the relevant NHS services and support in their area would have to be available with every test. People who used HIV self-test kits would then have access to face-to-face counselling.

Although it is a possibility that some individuals would not arrange a second test, this situation might also apply in medical settings, in which a proportion of people will not return to collect their test results.²⁰ Studies in the USA in people who used the home-sample-collection HIV test showed that many of those with positive results took up referrals for follow-up care.¹⁹ Although these people would have received their results from telephone counsellors, these referrals show willingness of those who have been tested to go to a health-care provider for further care.

Other concerns raised by self-tests are accuracy and the ability of people to provide adequate samples for testing. The test discussed by the FDA in November, 2005, was the OraQuick rapid HIV test (Orasure Technologies, Bethlehem, PA, USA), an oral-fluid testing system for which the individual takes a swab at home and the result develops within 20 min. This test was licensed for use in clinical and community health-care settings in the USA in 2004,²⁰ but there have been concerns about unacceptable numbers of false-positive results generated.⁶ OraQuick therefore might not have the required accuracy for a self-test for HIV. However, other methods will be developed and we can reasonably predict that a test will soon meet required standards of accuracy. If we can agree in principle that self-tests for HIV are ethically acceptable and

desirable, the law should be changed so that the process of scrutinising self-tests can begin.

Accuracy of an HIV test can also be affected by the ability of the person doing the test to collect the sample and interpret the results correctly. Therefore, self-tests for HIV might not be suitable for home use. For instance, false results produced by the inexperienced use of the test could cause high personal distress in the case of false-positives, or increased health risks in false-negatives.³ However, Branson¹⁹ noted in his study of the home-sample-collection HIV test that people were able to use such tests to produce accurate results.¹⁹ Spielberg and colleagues⁴ showed high congruence between laboratory tested results and home results. The evidence so far suggests that people's ability to use self-test kits need not be a major obstacle to their introduction.

The final concern about self-tests for HIV is the possibility of abuse⁵—ie, the testing of someone without their consent, either secretly or under duress. This undoubted drawback with self-testing does not apply to tests done in a medical setting. A solution would be to make testing for HIV by non-health care professionals without their consent illegal, as is being done for non-consensual DNA testing.²¹ Although such a law could not prevent testing, it would stop the results being used legally (eg, for employment dismissal). The effect of self-testing for HIV on other areas such as domestic violence would also need to be closely monitored when self-tests are piloted.¹⁷

HIV testing practices have changed substantially since self-tests were made illegal in the UK. With the incontrovertible benefits of increasing the numbers tested for HIV, the acceptability of self-tests should be reconsidered. If practitioners truly believe in patient autonomy, people should be allowed to choose where, when, and how they are tested for HIV, where the technology exists. When appropriate self-test kits become available, the UK needs to be in a position to benefit from their use.

Conflict of interest statement

I declare that I have no conflict of interest.

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