

HIV Home Testing Kits

Time to legalise and regulate

Overview

The HIV Testing Kits and Services Regulations 1992 state that 'a person who sells or supplies an HIV testing kit, or any component part of such a kit, to a member of the public shall be guilty of an offence.' The regulations require HIV testing services to be provided only by or under the direction of a registered medical practitioner.

THT believes that this ban should be repealed to give people the choice to test themselves for HIV in their own home. Home testing kits have an important part to play in reducing undiagnosed HIV and thereby reducing the HIV epidemic. Early diagnosis saves the NHS money and home testing could further reduce the cost of testing in clinical settings. Some people do not access testing services within the existing system. Others already buy illegal home testing kits over the Internet from overseas, which are not subject to UK regulation.

The need to increase testing options

26% of people with HIV in the UK do not know they have the virus. They are statistically far more likely to pass the virus on to others and may not be benefitting from the HIV treatment they need to stay well. It is estimated that someone with undiagnosed HIV is three and a half times more likely to infect someone else, compared with someone who has been diagnosed.

Demand for home testing kits

Evidence suggests that some people at risk of HIV would be more likely to test, or to test more regularly, if they could test themselves at home. Reluctance to test in a clinical setting can typically be due to time pressure, the stigma of being seen at a GUM clinic or discomfort when talking about sexual history with a medical practitioner. Others, including sex workers and people in serodiscordant relationships, want to test more regularly due to their increased risk of HIV exposure.

THT has surveyed over 650 people on attitudes to home testing, targeting groups at risk of HIV and people living with HIV. Results demonstrate demand for testing kits and suggest their legalisation could increase testing and reduce undiagnosed HIV:

- 35% of respondents living with HIV (58 of 167) thought they would have been diagnosed earlier if home testing kits were available. This rose to 44% of those who were diagnosed late (with a CD4 count <350).
- Of respondents who last tested negative or had never tested, 62% would consider using home testing kits if they were legally available and regulated. 51% think they would test for HIV more often.
- Of gay men who last tested negative or had never tested, 3% had used a home testing kit before. 65% would consider using a home testing kit. 60% think they would test for HIV more often if home testing kits were available.

The HIV and sexual health charity for life

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The UK Gay Men's Sex Survey 2008 (Sigma Research, October 2010) surveyed 7,500 gay men. 0.5% had their last test using an illegal home testing kit. 5.9% said their preferred way to test in future would be home testing.

Current availability of home testing kits

It is essential that people who test for HIV at home are provided with appropriate information, including on access to post-test counselling, particularly if the result is positive. Safer sex messages are important for all test users. Tests must be of a high quality, particularly to avoid false positive results.

However, such tests are not provided with the market for home testing kits that already exists despite the ban. Kits are bought from overseas over the Internet from illegal suppliers. Many individuals are unaware that such kits are both illegal and unregulated. Our research shows that these come without vital information on their use and support around results.

In January 2011, THT assessed the top three affordable (less than £30) home testing kits that appear via an Internet search. Two of these contained a testing device which states that it is intended for professional use only on the package. These contained only basic information on HIV transmission and the window period. None of the tests offered advice on safer sex. For those testing positive, there was either no advice whatsoever, or just advice to 'consult your doctor'. There was no further provision of or direction to other information, advice or support.

Support and advice

THT believes that whether someone is testing in a clinic or at home, pre- and post-test support and advice should be available to them. There is concern that legalising home testing kits would deny people immediate face-to-face support after a positive test result. However, we are very concerned that people have no access to support and advice from the illegal kits that are already available. Regulation of kits should ensure such information is provided, including appropriate contact details if the test is reactive.

Many people with HIV report experiencing shock immediately after their test result and only being receptive to face-to-face counselling some time later. Furthermore, an HIV diagnosis should no longer be perceived as a 'death sentence' as it may have been when the regulations were passed in 1992. Notably, similar concern was also expressed in opposition to legalisation of home pregnancy tests in the 1970s.

As part of THT's survey on home testing kits, we asked people about the need to obtain their result from a medical professional. Most people agreed that 'it is important that somebody is offered appropriate support and advice after a positive HIV diagnosis, but they should be able to obtain their result independently'.

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Home testing kits in other countries

Home testing kits are already legally available in other countries, including the Netherlands, Hong Kong and New Zealand. Kits are regulated and are typically bought from pharmacies or online.

Legalisation is expected shortly in the United States. Since 2005, the Food and Drug Administration (FDA) has worked with a leading testing kit manufacturer to develop an acceptable kit for the 'over the counter' market. Following clinical trials, FDA approval is expected in early 2012.

Conclusion

Legalisation and regulation of home testing kits would be congruent with broader government policy to increase testing and provide greater patient choice. Advances in testing technologies, the increasing online availability of unregulated home testing kits and evidence from trials in the United States have led to a growing consensus in the UK that the Government should repeal the existing ban and undertake a process to develop standards for a home testing kit for HIV that could be approved in the UK.

THT asks that the Government reform the HIV Testing Kits and Services Regulations to repeal the ban on supplying an HIV testing kit to a member of the public for personal use. This should be subject to NICE devising a standard that would ensure only safe, reliable kits with appropriate information are sold, and subject to regulation by the Medicines and Healthcare products Regulatory Agency.

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