

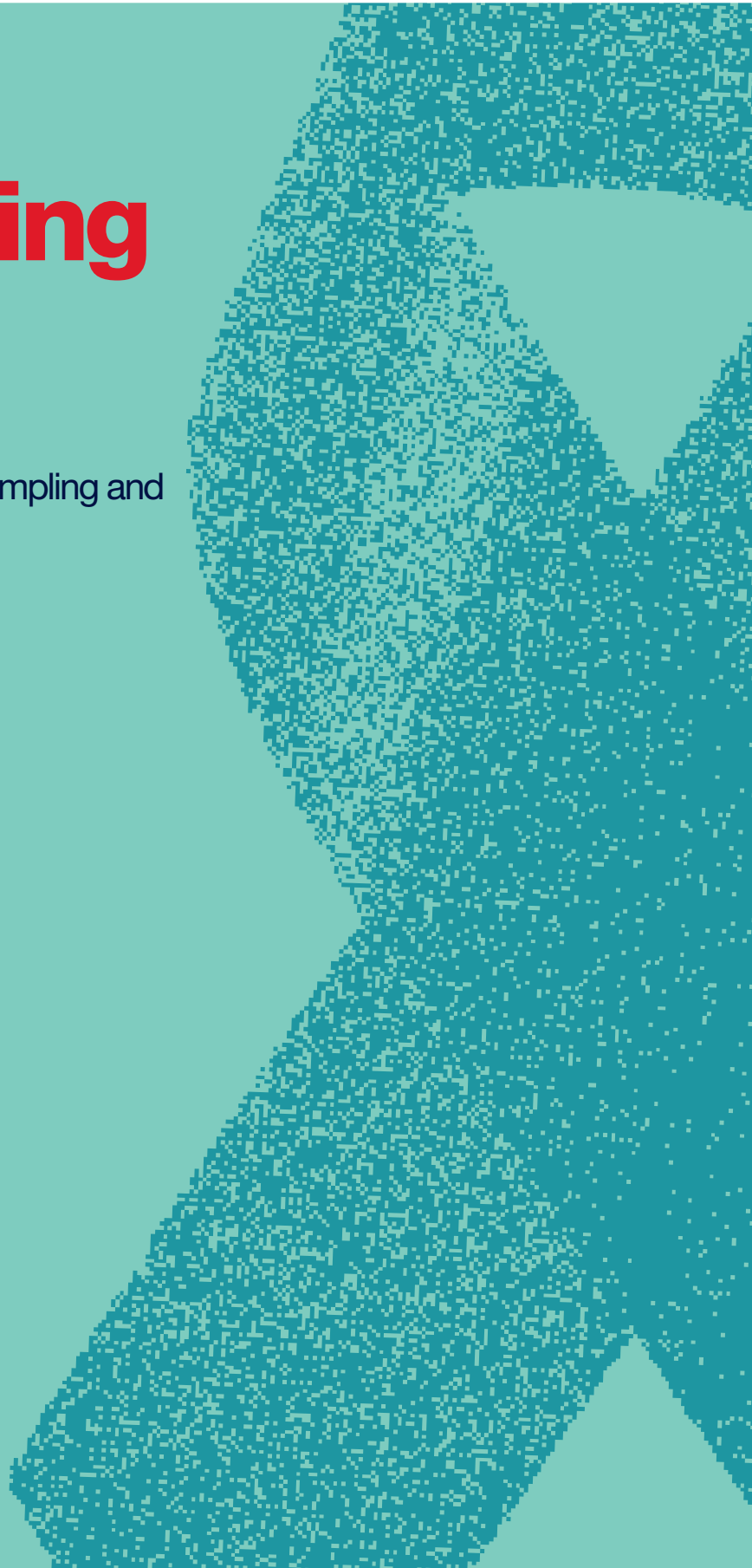
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Report: September 2008

Home Testing for HIV

A position paper by NAT on home sampling and self-testing for HIV in the UK



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Introduction

Technologies that enable rapid and accurate HIV testing are increasingly becoming available. Yet there are still lower levels of HIV testing in the UK than in many other countries. In the UK, it is estimated that a third of people with HIV are undiagnosed and a third of newly diagnosed HIV-infected adults are diagnosed late.¹ Barriers to testing include privacy concerns, stigma, transport costs, long waiting times and restricted clinic opening hours. Home sampling and self-testing for HIV have the potential to increase uptake and early diagnosis, and reduce the proportion of late diagnosis.

NAT (National AIDS Trust) is the UK's leading charity dedicated to transforming society's response to HIV. We provide fresh thinking, expert advice and practical resources. We campaign for change. One strategic aim of the organisation is early diagnosis of HIV through ethical, accessible and appropriate testing, for both individual and public health benefits.

This position paper begins with an executive summary of recommendations. It then provides an overview of home sampling and

self-testing for HIV and outlines issues for consideration for each testing method. Finally, it identifies recommendations with areas for further action.

Executive summary of recommendations

HIV testing needs to be more accessible so as to reach the significant amount of unmet need in the UK. Testing strategies must offer people real choices which meet their different and changing needs, support their rights and address the contexts in which decisions are made. Home sampling and self-testing for HIV could be an important part of testing strategies in the UK.

Home sampling recommendations

- Home sampling for HIV should be piloted on the National Health Service (NHS). In particular, this could include the offering of home sampling tests through genitourinary medicine (GUM) clinics and other sexual health settings. Such pilots should be closely monitored and could yield important information about the uptake, feasibility and effectiveness, including cost-effectiveness, of home sampling for HIV in the UK.

- Blood-based home sampling for HIV should be introduced in the UK to increase even further the reliability of home sampling test results.

Self-testing recommendations

- The Department of Health HIV Testing Kits and Services Regulations 1992 (Statutory Instrument 1992 No. 460) should be amended to permit and regulate self-testing kits which would allow the Government to ensure proper quality control and management of self-testing in the UK.
- The uptake of self-testing for HIV in the UK should be closely monitored, as well as any possible abuses of such tests.
- Manufacturers of any self-tests for HIV should be required to provide easy access to post-test counselling as an integral part of their testing service.
- Further UK-based research is required on the acceptability of self-testing for HIV, the impact of self-testing on risk reduction behaviours and improving access into follow up care.



Home sampling and self-testing

There are two types of home HIV tests.

- ▶ The first type is referred to as a home sampling test (sometimes called home screening test). This type of test requires that a person purchase a kit, for example at a chemists or online, and take a blood or saliva sample in their own home. The individual then mails the sample to a laboratory and later receives their results via telephone or online. If the test produces a reactive result,² the person is strongly advised to seek a confirmatory test in a clinic to diagnose HIV. Home sampling for HIV is legal in the UK.
- ▶ The second type of test is known as a home self-test, and is similar in approach to a home pregnancy or diabetes monitoring test.

This method is a rapid HIV test conducted by the person in their home. The individual buys the self-testing kit, for example at a chemists or online, takes a blood or saliva sample and interprets their own results within minutes. Instructions for follow up and sources of support may be provided in the kits, by telephone or online if a test produces a positive result. A confirmatory test in a clinic should be sought to diagnose HIV. Self-testing for HIV is illegal in the UK.

Home sampling for HIV in the UK

The Department of Health HIV Testing Kits and Services Regulations 1992 do not prohibit home sampling tests in the UK.³ One private company, Dr Thom, who is registered with the Healthcare Commission, is providing home sampling kits for HIV for order through the internet.⁴

1: Diagnosis after which antiretroviral treatment should have been initiated. Currently, this is after an individual's CD4 cell count has fallen below 200 cells/mm³.

2: A reactive result means that the laboratory cannot rule out that the person has HIV.

3: Department of Health (1992) *HIV Testing Kits and Services Regulations 1992*, www.opsi.gov.uk/si/si1992/Uksi_19920406_en_1.htm.

4: www.drthom.com.

5: Wright (2006) Home testing for HIV, *New England Journal of Medicine*, 354: 437-440.

6: *Ibid.*

Situation in the US

Home sampling

A ban on the advertising and sale of HIV sampling kits was lifted in the US in 1995 when the US Food and Drug Administration (FDA) decided that access to sampling kits could encourage previously unreachable groups to test for HIV. There is currently one company in the US, Home Access, that offers an FDA-approved home sampling test for HIV. This test uses a finger prick process for home blood collection. It also offers telephone-based counselling.

Self-testing

There are several HIV self-testing kits being advertised in the US. These are not approved by the FDA and are illegal.

In 2005, the FDA convened a meeting of experts to discuss the issues raised by a self-test for HIV using saliva. The meeting was called because the manufacturers of the test, OraSure, indicated that they would seek over-the-counter approval for the test to be sold in chemists. This test was already licensed for use in clinical healthcare settings in 2004, but there were concerns about the high number of incorrect positive results.⁵

Despite concerns, there was strong support for home HIV self-testing among experts at the meeting. Only two of the 20 participants voiced concern about bringing a home self-test to market. Others argued that it was long overdue.⁶ The panel recommended additional studies on whether people could perform the test correctly and what psychological risks exist for those who test HIV-positive. OraSure plans to apply for FDA approval for over-the-counter sales after additional studies scheduled through 2008 are completed.

Home sampling for HIV in the UK

Dr Thom collaborates with the Terrence Higgins Trust (THT) to promote the home sampling testing method using a saliva-based test.⁷ Information is provided on both Dr Thom and THT's websites about, for example testing for HIV, home sampling, its accuracy and the 'window period' – the time it takes for a test to recognise HIV antibodies in the body. Home sampling kits are available for purchase through links on both websites.

Saliva tests can detect signs of an immune response to HIV but cannot diagnose. This is because home sampling kits using saliva are less reliable than those using blood. Tests using oral fluids can correctly identify between 95-97 per cent of known positive saliva samples and between 90-95 per cent of HIV negative saliva samples.⁸ A reactive result from a saliva-based home sampling test suggests an individual may be HIV-positive and a confirmatory blood test in a clinic is always needed to diagnose HIV.

Home sampling for HIV using blood, however, is as accurate as a similar test conducted in a clinic. HIV home sampling using blood is able to correctly identify 100 per cent of known positive blood samples, and 99 per cent of HIV negative blood samples.⁹ However, a confirmatory test in a clinic is needed to diagnose HIV and is important to ensure appropriate follow up and support. Home sampling for HIV using blood is currently not offered by UK-based companies.

There is little data in the UK as to the uptake of home sampling for HIV. However, there is some evidence on this from the US. Within a year of FDA approval, more than 175,000 people purchased home sampling kits.¹⁰ Two surveys of HIV home testing methodologies conducted between 1999 and 2000 found that the concept of home sampling was acceptable to people at risk for HIV, and to people who had never previously been tested.^{11, 12} Post-marketing studies of home sampling also show that among those newly diagnosed as HIV-positive, 49 per cent were first-time testers, indicating that home sampling is acceptable, particularly among those who would not normally access testing.¹³

In addition, effectiveness of home sampling has been examined for other sexually transmitted infections (STIs). For example, studies in Denmark and Sweden showed that this type of screening for Chlamydia was effective, feasible and may also encourage young people to be tested.^{14, 15}

This suggests that home sampling for HIV could be an innovative part of prevention and treatment strategies and contribute to early diagnosis, particularly among people at risk of infection or among those who would not normally access testing. This could translate

How does home sampling for HIV in the UK work?

The description below outlines the process an individual in the UK would take based on Dr Thom's home sampling kit for HIV using oral fluids.

Collecting a saliva sample

Wait at least 20 minutes since you last had something to eat or drink, then gather saliva from your mouth. Unwrap the saliva collection device and place the end with the cotton pad under your tongue. Close your mouth and keep the pad under your tongue until you see the other end of the device turn blue. This normally takes about five minutes.

Sealing it and posting it

When the device has turned blue, push the device into the tube provided, which already has a small amount of liquid in it. Put the top back on the tube to seal it. Roll up the sealed tube inside the absorbent cloth pouch and put it in the clear plastic bag provided. Put the closed bag in the box with a completed customer information form (details requested include name, sex, date of birth and date the sample was collected). Close the box and apply the security seal. Post the box to reach the laboratory within three to four days. The sample is then analysed by trained clinicians.

Getting the results

Results are uploaded onto a secure online patient record, accessible with your unique login and password provided in the kit. If the sample took too long to reach the laboratory or if the laboratory cannot rule out that you have HIV, you will be contacted by telephone with information about the need to access confirmatory testing in a clinic, told what a reactive result means and provided with initial counselling. Information about how to access advice and support on sexual health and HIV is also provided in the kit.

into both individual and public health benefits. Additional research is needed on the uptake of home sampling for HIV among individuals in the UK.

Ways to promote and roll out home sampling for HIV, particularly by the NHS including in genitourinary medicine (GUM) settings, also need to be examined. Home sampling for HIV could also be an important screening tool that may free up valuable GUM outpatient clinic resources. Monitoring data show waiting times for GUM services in the UK have decreased in recent years, but this varies across regions and about 15 per cent of patients in England are still not seen within 48 hours.¹⁶ Further research is needed to assess the cost-effectiveness of home sampling for HIV, particularly in GUM settings.

Recommendations

- Home sampling for HIV should be piloted on the NHS. In particular, this could include the offering of home sampling tests through GUM clinics and other sexual health settings. Such pilots should be closely monitored and could yield important information about the uptake, feasibility and**

effectiveness, including cost-effectiveness, of home sampling for HIV in the UK.

- Blood-based home sampling for HIV should be introduced in the UK to increase even further the reliability of home sampling test results.**

Self-testing for HIV in the UK

Unlike home sampling, self-testing for HIV is illegal in the UK.¹⁷ This includes the sale, supply and advertising of self-testing kits. However, with the internet, it is likely that those living in the UK would not have trouble accessing such tests. A study in the UK found that home self-testing kits for STIs including HIV could easily be obtained on the internet by both clinicians and members of the public.¹⁸

Self-testing kits currently sold on the internet, of which there are several, are not subject to any form of UK quality control and may not carry information about sources of support on HIV and sexual health in the UK. There is no data on uptake of unregulated self-tests for HIV in the UK, other than the above mentioned study that shows such tests are easily accessible.

Some HIV organisations are calling on the Government to change the law to let people buy and use self-testing kits for HIV. These organisations say a safe alternative to unregulated kits from the internet should be offered for those who want to self-test for HIV, and that amending the 1992 Department of Health Regulations would allow the Government to ensure proper quality control and management of home testing in the UK.¹⁹ Others oppose the sale of self-testing kits in the UK because of the potential that individuals may not perform their test or interpret their results correctly and the lack of post-test counselling.²⁰

These issues raise a number of questions: Will self-testing for HIV be acceptable among people at risk? Will untrained people be able to perform and interpret self-tests accurately? How accurate are self-test results? How would self-testing impact on HIV risk behaviours? How will people with a positive self-test result access counselling and support? What about confidentiality? These questions are discussed in further detail below.

7: www.tht.org.uk.

8: Dr Thom, www.drthom.com/services/services_sti_testdet.php?TestNo=2&cat=2&subcat=10.

9: US Food and Drug Administration (2008) *Testing yourself for HIV-1, the virus that causes AIDS fact sheet*, www.fda.gov/cber/infosheets/hiv-home.htm.

10: Branson (1998) *Home sample collection tests for HIV infection*, JAMA, 280: 1699-1701.

11: Spielberg et al (2003) *Overcoming barriers to HIV testing: Preferences for new strategies among clients of a needle exchange, a sexually transmitted disease clinic, and sex venues for men who have sex with men*, Journal of Acquired Immune Deficiency Syndrome, 32: 318-327.

12: Skolnik et al (2001) *Deciding where and how to be tested for HIV*, Journal of Acquired Immune Deficiency Syndrome, 27:292-300.

13: Ibid.

14: Andersen et al (2002) *Population-based strategies for outreach screening of urogenital chlamydia trachomatis infections*, The Journal of Infectious Diseases, 185: 252-258, www.journals.chicago.edu/doi/pdf/10.1086/338268.

15: Novak et al (2006) *Simplifying chlamydia testing: An innovative chlamydia trachomatis testing approach using the internet and a home sampling strategy population-based study*, Sexually Transmitted Infections, 86: 142-147, sti.bmj.com/cgi/content/abstract/82/2/142.

16: Monitoring data on GUM waiting times from the Department of Health Sexual Health Team, September 2008.

17: Department of Health (1992) *HIV Testing Kits and Services Regulations 1992*, www.opsi.gov.uk/si/si1992/Uksi_19920406_en_1.htm.

18: British Association for Sexual Health and HIV and American Sexually Transmitted Diseases Association Third Joint Conference (2008) *Home testing for STIs: Results of a study examining the feasibility and simplicity of obtaining home testing kits via the internet*, www.bashh.org/spring_meeting/new_york_08/Program_Web_full2.pdf.

19: For example, see Terrence Higgins Trust, www.tht.org.uk/mediacentre/pressreleases/2007/september07/september12.htm.

20: For example, see Avert, www.avert.org/hivtesting.htm.

Self-testing for HIV in the UK

Will self-testing for HIV be acceptable among people at risk?

Increasing the numbers of people at risk tested for HIV, and decreasing the proportion of people diagnosed late, is partly dependent on whether self-testing for HIV is acceptable among people at risk.

There is little UK evidence on this issue. However, a US survey on self-testing found that over a third of respondents who had never been tested for HIV were willing to use instant home tests and would likely be tested in the next 12 months.²¹ Another US study examined the acceptability and feasibility of self-testing among people who already knew their HIV status. 240 HIV-positive individuals took self-tests and interpreted the results. Over 60 per cent of individuals reported that they would have been supportive of finding out their HIV-positive status at home using a self-test.²²

These studies indicate that self-testing for HIV is acceptable among those who have never tested before and among people at risk. There is a fundamental need to extend HIV testing beyond clinical settings and make testing more accessible to reach the significant amount of unmet need. Testing strategies must offer people real choices which meet their different and changing needs, support their rights and address the contexts in which decisions are made.

Self-testing could expand the reach of HIV testing, increase early diagnosis and reduce the proportion of those diagnosed late, while supporting

FACT

Some countries have approved the sale of self-testing kits for HIV. For example, the MiraTes HIV rapid home self-test has been approved for over-the-counter sale in chemists in the Netherlands since 2000. Another rapid test, produced by MedMira, is marketed over-the-counter in Hong Kong. Both are blood-based and produce results within minutes. There is little data available on the impact these approved self-testing products are having on HIV diagnosis in the Netherlands and Hong Kong. Other health authorities in countries including Australia, France, Germany, Switzerland and the US are considering or have not yet approved over-the-counter self-testing kits for HIV.

a person's right to choose how to be tested. This could translate therapeutic advances and diagnosis-related behaviour change into individual and public health benefits. Additional research would be helpful on the acceptability and feasibility of self-testing for HIV, specifically among individuals in the UK.

Will untrained people be able to perform and interpret self-tests accurately?

There has been concern that untrained people may not be able to perform or interpret self-test results accurately.

However, the 240 HIV-positive people in the Spielberg 2006 study cited above were also tested on their ability to undertake and interpret multiple oral fluid and finger-stick test results based on the simple written instructions that accompanied a self-test. The concurrency with laboratory-tested results was 94 per cent for oral fluid and 95 per cent for finger-stick blood samples. Post-test interviews found that those who made mistakes in interpreting their results had not read the instructions and admitted to guessing the results.

21: Phillips (2003) *Willingness to use instant home HIV tests: Data from the California Behavioural Factor Surveillance Survey*, American Journal of Preventive Medicine, 24: 340-348.

22: Spielberg et al (2003) *HIV home self-testing: Can it work?*, National HIV Prevention Conference; Atlanta, GA, US: 27-30 July 2003, Abstract #1007.

23: US Food and Drug Administration (2008) *Testing yourself for HIV-1, the virus that causes AIDS fact sheet*, www.fda.gov/cber/infosheets/hiv-home.htm.

24: Dr Thom, www.drthom.com/services/services_sti_testdet.php?TestNo=2&cat=2&subcat=10.

Although a small proportion may misinterpret their test results as shown in the study above, which is a relevant issue of which to be aware, research indicates that most untrained people are likely to be able to perform and accurately interpret self-testing results for HIV. Therefore, self-tests for HIV should not be prohibited on this basis.

How accurate are self-test results?

The Medicines and Healthcare Products Regulatory Agency (MHRA), an agency of the Department of Health, is responsible for regulating the safety, quality and performance of self-test kits. Kits sold in the UK must comply with Medical Devices Regulations 2002. The regulations, applicable to kits used to test human samples such as blood and saliva, ensure that all test kits are safe to use and perform as intended by the manufacturer.

Approved home tests for HIV using blood are as accurate as those offered in clinics. Clinical studies in the US have shown that approved HIV testing of blood is able to correctly identify 100 per cent of known positive blood samples, and 99 per cent of HIV negative blood samples.²³ Testing of saliva is less reliable than that of blood. Tests using oral fluids can correctly identify between 95-97 per cent of known positive saliva samples and between 90-95 per cent of HIV negative saliva samples.²⁴ Widespread HIV testing in low-risk populations is likely to yield a proportionally higher number of false positives. This underlines the importance of confirmatory clinic-based tests if a reactive result is received from a home test.

Self-testing kits for HIV currently sold on the internet are illegal and not subject to any form of UK quality control, nor do many of them carry information about sources of follow up or support. However, amending the HIV testing kits and services

regulations to permit and regulate self-testing would allow the Government to oversee quality control and management of self-testing kits in the UK to ensure accuracy and confidence in them.

How would self-testing impact on HIV risk behaviours?

Although privacy and convenience are clearly benefits, self-testing at home will prevent new cases of HIV only if it encourages more people to test (which is possible from the evidence shown above), and if the people who learn their HIV-positive status seek follow up care and reduce their risk behaviours.

Research findings have shown that a powerful motivator for behaviour change is knowledge of HIV status. People with positive test results change towards safer sexual behaviour.^{25,26,27} One observational study also found people who are aware of their positive HIV status are not only more likely to practise safer sex, but seek medical care and plan for the future.²⁸

Since knowledge of HIV status reduces risk behaviours, there is a clear benefit to permitting and regulating self-testing in the UK, and integrating it into prevention and treatment strategies. However, further research is required on whether or not self-testing would increase the number of people who know their HIV status in the UK, and among people with continued exposure to HIV. It would also be helpful on whether HIV self-testing increases the number of people who test at regular intervals.

Medical Devices Regulations

The Medical Devices Regulations 2002 divide tests into categories according to the degree of perceived risk. Perceived risk is based on who the user is and the potential impact of the test failing to perform as intended. The highest risk category includes tests for HIV, Hepatitis and those that determine blood groups. Lower risk tests include those for blood glucose levels.

In addition, self-testing kits, where a test is carried out at home, form a further discrete category under the regulations. For home self-testing kits, the manufacturer submits details of their test to an independent body designated and monitored by MHRA, which ensures that the test performs as claimed when used by a non-professional. Specific self-tests that carry higher risks, such as for HIV, must also undergo a more stringent audit process.

25: US Centres for Disease Control and Prevention (2004) *High-risk sexual behaviour by HIV-positive men who have sex with men 2000-2002*, Morbidity and Mortality Weekly Report, 53: 891-894.

26: Shisana et al (2004) *Does knowing one's HIV status matter in HIV prevention?* International AIDS Conference, Bangkok, abstract ThOrC1414.

27: Leaity et al (2000) *Repeat HIV testing: high-risk behaviour or risk reduction strategy?* AIDS, 14: 547-52.

28: US Centres for Disease Control and Prevention (2000) *Adoption of protective behaviours among persons with recent HIV infection and diagnosis – Alabama, New Jersey and Tennessee*, Morbidity and Mortality Weekly Report, 49: 512-515.

Self-testing for HIV in the UK

How will people with a positive self-test result access counselling and support?

In response to calls to increase the numbers of at-risk people tested for HIV and reduce waiting times, the British Association of Sexual Health and HIV (BASHH) guidelines suggest that clinics stop routine pre-test counselling.²⁹ Before taking a test, people are instead recommended to have a pre-test discussion, to ensure informed consent for the test.

Although pre-test practice is changing in the UK, post-test counselling is still an important part of HIV testing. Some health professionals have argued that people receiving a positive HIV test on their own would suffer greater distress and anxiety than those receiving their results in healthcare settings.³⁰ For example, fears were raised when the FDA was considering home sampling in the early 1990s. However, studies in the US on the implementation of home testing methodologies for which telephone counselling was available did not show any adverse consequences such as increased suicides associated with their introduction.³¹

Self-testing for HIV also does not necessarily mean there would be no counselling or support. Although no face-to-face counselling is immediately provided along with the test result, telephone or web-based counselling could be available. In addition, in

the UK, the Parliamentary Office of Science and Technology says 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.³²

Counselling would also be available when people sought a confirmatory test. Although there is the possibility that some people would not arrange a second test (as can also happen in a clinical setting), a MiraTes company survey of those who tested positive using their self-tests for HIV in the Netherlands showed that all had sought follow up treatment.³³

Although not a reason to prohibit self-testing for HIV, this raises a need for further work on how to improve access into follow up care. It suggests the need for clear information during the self-testing process on the benefits of early diagnosis and effectiveness of treatment, as well as on the pathways into care. Other innovative approaches to pre-test discussion and post-test counselling, such as picture or word-based brochures as well as 24-hour telephone advice lines or web-based counselling, could be further developed and evaluated for appropriateness and effectiveness in the UK.

What about confidentiality?

Finally, there is some concern about the possible abuse of self-tests for HIV. This includes the testing of someone without

their consent, for example by employers during the hiring process, insurers prior to signing a contract or police officers during checks.

One solution that has been suggested would be to make testing for HIV by non-healthcare professionals without the consent of the person being tested illegal, as is being done for non-consensual DNA testing in the US.³⁴ It may well be, however, that 'consent' becomes a difficult concept where willingness to test might be necessary to secure insurance or employment, for example. In which case, it might be better simply to make any use of self-test kits by third parties illegal. This is precisely where further consideration and new regulations would be useful.

There has also been concern raised about the impact of self-testing for HIV on the potential for domestic violence. Whilst this issue is one which would need to be closely monitored, it is part of a wider question of violence, abuse and hate crime in response to positive diagnosis disclosure, and is best addressed by education and the criminal law.

Recommendations

- **The Department of Health HIV Testing Kits and Services 1992 Regulations should be amended to permit and regulate self-testing kits which would allow the Government to ensure proper quality control and management of self-testing in the UK.**

29: British Association of Sexual Health and HIV (2006) *United Kingdom National Guidelines on HIV Testing*, www.bashh.org/guidelines/2006/hiv_testing_june06.pdf.

30: Spielberg et al (2001) *Slow diffusion of home HIV-specimen collection provider concerns at odds with client preferences*, *Sexually Transmitted Diseases*, 28: 51-57.

31: Branson (1998) *Home sample collection tests for HIV infection*, *JAMA*, 1998, 280: 1699-1701.

32: UK Parliamentary Office of Science and Technology (2003) *Medical self-test kits*, Postnote, www.parliament.uk/post/pn194.pdf.

33: Miedema, Quality Manager and MiraTes founder, response to questions about accessing treatment following a positive MiraTes self-test result, www.martinfrost.ws/htmlfiles/aidstest1.html.

34: Frith (2007) *HIV self-testing: A time to revise current policy*, *Lancet*, 369: 243-245.

35: Currently, home sampling using saliva is available in the UK and home sampling using blood is available, for example, in the US. This is not due to legislative differences in the two countries, but rather for commercial and logistical reasons. It was suggested in an interview with Dr Thom that home sampling using blood collection could soon be available in the UK.

- ▶ **The uptake of self-testing for HIV in the UK should be closely monitored, as well as any possible abuses of such tests.**
- ▶ **Manufacturers of any self-tests for HIV should be required to provide easy access to post-test counselling as an integral part of their testing service.**
- ▶ **Further UK-based research is required on the acceptability of self-testing for HIV, the impact of self-testing on risk reduction behaviours and improving access into follow up care.**

Conclusion

Innovative testing strategies for HIV, including home sampling and self-testing, are needed for those who are unwilling or unable to access clinic-based services. These types of tests could offer greater privacy and convenience for individuals. In addition, having reliable, accurate and regulated home testing kits available in the UK could reduce both undiagnosed infection and onward transmission, as HIV is often passed on by people who do not know they have it.

When the HIV Testing Kits and Services Regulations were drafted in 1992, having HIV was fundamentally different. Today, increasingly effective treatments mean that people can live long, healthy lives with HIV, which is now a manageable condition for many. Reliable and accurate home sampling and self-testing for HIV have the potential to be innovative and effective components to HIV-prevention and treatment strategies in the UK, translating into individual and public health benefits.

TABLE

Summary of home sampling for HIV in the UK and US and of self-testing for HIV

	Saliva-based home sampling (UK)	Blood-based home sampling (US)	Saliva or blood-based self-testing
Method	Sampling device purchased; saliva sample ³⁵ taken at home and posted to a laboratory for testing	Sampling device purchased; blood sample ³⁵ taken at home and posted to a laboratory for testing	Kit purchased for taking a saliva or blood sample and testing it at home
Notification	Reactive results given by telephone and negative results given online	Results given by telephone	Results produced and interpreted at home
Availability	Legal in the UK and approved test available online for £34	Legal in the US and sold in shops, online or by telephone for between \$40 and \$60	Illegal in the UK; approved, for example in the Netherlands and Hong Kong but not yet approved for over-the-counter sale in many other countries including the US
Potential for mistakes	Oral sample may be taken incorrectly or takes too long to reach the laboratory, possibly leading to a false result	Low potential for mistakes as blood sample is clearly visible on the special paper, however false results are possible	Test may be performed or interpreted incorrectly, possibly leading to a false result
Reliability	Approved home sampling tests using oral fluids can correctly identify between 95-97 per cent of known HIV-positive saliva samples and between 90-95 per cent of negative saliva samples A reactive result from a saliva-based home sampling test suggests an individual may be HIV-positive and a confirmatory test in a clinic is always needed to diagnose HIV	Approved blood-based home sampling is able to correctly identify 100 per cent of known HIV-positive blood samples and 99 per cent of negative blood samples A confirmatory test in a clinic is always needed to diagnose HIV	Approved home self-tests using oral fluids can correctly identify between 95-97 per cent of known HIV-positive saliva samples and between 90-95 per cent of negative saliva samples Approved blood-based home self-tests for HIV are able to correctly identify 100 per cent of known HIV-positive blood samples and 99 per cent of negative blood samples A confirmatory test in a clinic is always needed to diagnose HIV
Window period	Information available online when purchasing; test is unlikely to pick up signs of HIV infection in the first three months after infection	Information available online when purchasing; test is unlikely to pick up signs of HIV infection in the first three months after infection	Information could be available online when purchasing and in the kit brochure
Pre-test discussion	Optional, by telephone	Optional, by telephone	Possibly optional, by telephone
Post-test counselling	Available, by telephone and in-person through confirmatory testing in a clinic	Available, by telephone and in-person through confirmatory testing in a clinic	Possibly available, by telephone and in-person through confirmatory testing in a clinic

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About NAT

NAT (National AIDS Trust) is the UK's leading charity dedicated to transforming society's response to HIV. We provide fresh thinking, expert advice and practical resources. We campaign for change.

All of NAT's work is focused on achieving four strategic goals:

- ▶ Effective HIV prevention
- ▶ Early diagnosis of HIV through ethical, accessible and appropriate testing
- ▶ Equitable access to treatment, care and support for people living with HIV
- ▶ Eradication of HIV-related stigma and discrimination.

National AIDS Trust

New City Cloisters
196 Old Street
London EC1V 9FR

T : +44 (0)20 7814 6767

F : +44 (0)20 7216 0111

E : info@nat.org.uk

W: www.nat.org.uk

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