Article

HIV home testing – a problem or part of the solution?

J Gardner, MSc Med (Bioethics and Health Law)
Steve Biko Centre for Bioethics, School of Clinical Medicine, Faculty of Health Sciences, University of Witwatersrand, Johannesburg

Corresponding author: *J Gardner (Jillian.Gardner@wits.ac.za)*

In April 2010, South Africa launched an HIV Counselling and Testing (HCT) campaign that, among other things, sought to massively increase the numbers of people who test, know their HIV status and receive treatment. This is in line with the goals laid out in the country's National Strategic Plan (NSP) for HIV, Sexually Transmitted Infections and Tuberculosis, which aims to significantly reduce the number of new infections and expand access to appropriate treatment, care and support to people diagnosed with HIV.

The realisation of the NSP goals requires strategies that lead to a greater number of individuals getting tested. This article has one simple objective – to stimulate discussion and debate on the topic of HIV home testing, which the author postulates may be preferable to some people, largely because it enables individuals to perform some or all aspects of the test in locations chosen by them. In this way home testing has the benefit of potentially increasing the number of people who test, know their HIV status and consequently present for treatment. The article considers whether some of the reasons that are usually offered against this approach to counselling and testing are sufficiently justified in the South African context, and suggests that these reasons are not sufficiently justified and that this system of HIV testing could contribute towards achieving the goals set out in the country's NSP.

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In April 2010, South Africa launched a HIV Counselling and Testing (HCT) campaign that, among other things, sought to massively increase the number of people who test, know their HIV status and receive treatment. This is in line with the goals laid out in the country's National Strategic Plan (NSP) for HIV, Sexually Transmitted Infections and Tuberculosis,[1,2] which aims to significantly reduce the number of new infections and expand access to appropriate treatment, care and support to people diagnosed with HIV.

HCT is an umbrella term used to describe services that combine HIV counselling and testing.[3] South Africa's National Policy on HCT distinguishes between two types of counselling and testing services – those that are client-initiated and those that are provider-initiated.[3] Client-initiated counselling and testing, which is also called voluntary counselling and testing (VCT), involves individuals and couples actively seeking out these services. Provider-initiated counselling and testing (PICT), which is also referred to as routine offer of testing, involves HIV counselling and testing that is routinely initiated and recommended by healthcare providers to all clients attending healthcare facilities as a standard component of medical care. Both types of HCT services require informed consent, counselling, and confidentiality to be observed and to be implemented at every health facility.[3]

Realisation of the NSP goals requires strategies that lead to a greater number of individuals getting tested. The aim of the HCT campaign was to target 15 million South Africans for HIV testing by the end of June 2011. The campaign was based on a routine offer of voluntary HIV testing in a wide variety of settings, including health facilities.[3] Preliminary figures show that over 12 million people were counselled for HIV between April 2010 and June 2011. Of these, about 85% or 10.2 million accepted the HIV test. Around 1.7 million (17 - 18%) who tested were positive for HIV.[4] Despite the success of the campaign in making HCT increasingly available in South Africa, 15% of individuals who were offered the test exercised their right to not take it. Given the high rate of refusals, it seems safe to assume that facilities-based testing may not achieve adequate testing coverage.

This article has one simple objective – to stimulate discussion and debate on the topic of HIV home testing, which I postulate may be preferable to some people, largely because it enables individuals to perform some or all aspects of the test in locations chosen by them. In this way home testing has the benefit of potentially increasing the number of people who test, know their HIV status and consequently present for treatment. In order to stimulate debate and discussion on this topic, I consider whether some of the reasons that are usually offered against this approach to counselling and testing are sufficiently justified in the South African context. I suggest that these reasons are not sufficiently justified and that this system of HIV testing could contribute towards achieving the goals set out in the country's NSP. In the sections that follow I explain what HIV home testing involves and evaluate some of the arguments that have traditionally been put forward as reasons for opposing this approach.

HIV home testing

HIV home testing involves the sale of HIV home test kits, either over the counter, usually in pharmacies, or by mail order or online

from the manufacturer, to legally competent adults.[5] Under one system of HIV home testing, which may also be referred to as home use or self-testing, a person conducts a rapid antibody HIV test in their home or other private setting. The person takes either a blood or saliva sample and can interpret the result within minutes. In some ways, this form of home testing is not unlike home pregnancy test kits, which allow users to conduct and interpret the results and advise them to go for confirmatory tests. Under another form of HIV home testing, which may be referred to as the home sampling or home specimen collection system, a person can take a sample (usually a blood sample) and send it to a laboratory for testing. The results can be obtained telephonically a few days later. Users are offered pre- and post-test, anonymous and confidential counselling through both printed material and telephonic interaction. If the result is positive, a professional counsellor will provide emotional support and referrals.[6]

At the time of writing this article, HIV home testing has received limited approval in two countries in the world: the USA and the UK. In 1996 the US Food and Drug Administration (FDA) approved a form of HIV home testing that allows for test kits to be sold legally in the country over the Internet.[7] Only one company is allowed to offer the FDA-approved home sampling kit for HIV.[8] The kit consists of multiple components, including materials for specimen collection, a mailing envelope to send the specimen to a laboratory for analysis, and pre- and post-test counselling. The system uses a simple finger-prick process for home blood collection which results in dried blood spots on special paper. The dried blood spots are mailed to a laboratory with a confidential and anonymous personal identification number (PIN), and analysed by trained clinicians in a laboratory using the same tests that are used for samples taken in a doctor's office or clinic.[6] Test results are obtained through a toll-free telephone number using the PIN, and post-test counselling is provided by telephone when results are obtained. In the UK, one company reportedly offers home sampling services but uses oral fluid instead of blood. If the test result is positive the person will need a follow-up blood test at a clinic.[9]

Even though home testing for HIV is not illegal in South Africa, current HIV testing policy discourages the 'indiscriminate use and availability of home test kits' and supports the idea of not making HIV tests available to the public 'unless prescribed by a doctor or mental health professional and accompanied by pre- and post-test counselling'.[10]

In the following section I explore whether some of the objections to home testing can withstand closer scrutiny. I suggest that many of the concerns about HIV home testing can be avoided through careful planning, implementation, regulation and monitoring of the system.

Concerns about the reliability of testing instruments

The availability of access to potentially unreliable testing instruments is of grave concern. Despite controls in the USA and UK, unapproved HIV home test kits continue to be marketed and sold in a seemingly indiscriminate manner – over the Internet and in newspaper and magazine advertisements.[11] One of the worrying aspects of the unregulated use of home tests is that there is no guarantee that the test kit is genuine or will provide accurate results. Typically, customers cannot know for certain whether the testing instrument that comes in the kit they purchase is reliable. This means that they cannot know with any degree of certainty that the test results are correct.

This argument, however, implies that all HIV tests are unreliable and that no antibody test is 100% accurate, which surely cannot be true. In the USA, for example, manufacturers of approved test systems have demonstrated that the test system can accurately detect even low levels of antibodies to the HIV virus.[6] According to the FDA, clinical studies have also shown that their approved home collection test system can correctly identify 100% of known positive blood samples, and 99.5% of HIV-negative blood samples.[6] Although this applies in the USA, it is hard to see why a properly regulated system cannot serve to minimise the use of unreliable testing instruments and test kits in South Africa. A properly controlled system can potentially facilitate informed decision-making by consumers and protect them from unsafe or unreliable testing devices by, for example, approving only reliable test kits and educating and warning the public about the system and unreliable test kits.

Concerns about the potential for abuse

Often it is also argued that HIV home testing will create the possibility for abuse of individual rights. Situations could arise where especially vulnerable groups, such as employees, children and women in abusive relationships, are tested without their consent and experience violations of their privacy rights and thus become vulnerable to further abuse and harm. These are significant concerns; however, the likelihood of abuse occurring exists even in the current environment of VCT and PICT. Rather than serving as an objection against home testing, I suggest that this concern really makes clear the need to enforce existing statutory protection against unlawful testing and discrimination.

Consent- and counselling-related concerns

Perhaps the most fundamental arguments against home testing relate to concerns about the possible absence of counselling and informed consent. In South Africa, under both VCT and PICT approaches, the requirements of counselling, informed consent and confidentiality must be observed. HIV testing must always be voluntary and free of coercion.

The primary objective of counselling before an HIV test (i.e. pre-test counselling) is to facilitate informed decision-making about testing. It serves as a means to provide education and information about HIV transmission and prevention so that individuals can make informed choices about whether to take the test.[3] Pre-test

counselling may be conducted with groups, couples or individuals.[3] It is not clear whether this should necessarily occur face-to-face, although existing policy around testing seems to imply that this should be the case.[3]

Of particular concern with regard to home testing systems is the potential lack of post-test counselling. The purpose of post-test counselling is to inform individual clients of their test results, to offer them a comprehensive HIV prevention package, to encourage them to go for regular testing, to reduce the risk of transmission or acquisition of HIV, and to offer emotional and psychosocial support and referrals.[3] In terms of existing testing policy in South Africa, 'All clients, regardless of the outcome of the HIV test, should be offered and receive post-test counselling on an on-going basis as appropriate.'[3] The implication is that counselling, although it may arguably be non-directive and non-judgemental, is an obligatory requirement.

It is not unreasonable to wonder why counselling cannot occur in alternative forms such as through the use of written and audiovisual educational materials in appropriate languages, or over the telephone, both of which have been found to be valuable and effective tools for communicating information and test results for HIV. For example, one study demonstrated that people can receive HIV test results and referrals by telephone without adverse outcome,[12] while others found that the option of telephonic counselling significantly increased follow-up for HIV test results.[13,14] More recently, preliminary results of a randomised controlled pilot trial to test the effectiveness of informational videos about HIV and HIV testing found that patients who watched these videos demonstrated as good or better comprehension of rapid HIV testing fundamentals compared with patients who were assigned to the counselling group.[15] These findings suggest that these media can be effective substitutes for in-person HIV discussions. I am not suggesting that the 'traditional' mode of face-to-face counselling should be abandoned. The point is simply that some people may in fact prefer to not have to 'go' for counselling or may prefer to be counselled in other ways, and that the use of these media may be worth considering in an effort to increase the numbers of people who are counselled and offered HIV testing. Under the home testing system permissible in the USA, post-test counselling is in a sense obligatory, albeit it over the telephone, for those individuals who wish to receive their test results.

The idea behind informed decision-making is the enhancement of personal autonomy. But obligatory requirements as to how counselling should occur can have the effect of undermining the very principle that informed consent seeks to promote by deterring people from testing. The value of home testing lies in its potential to enhance personal autonomy and rights. This is because it offers users greater control over their lives. Respecting personal autonomy entails respecting the wishes of people about whether or not they will test, the conditions under which they choose to test, and whether they go for counselling. So, provided individuals make voluntary decisions based on accurate and appropriate information and understanding, their choices should ideally be respected. This perhaps should include the decision about which system of HIV testing they will utilise. While the need to obtain informed consent is appropriate and makes sense in settings where counselling and testing occur under the supervision of designated healthcare workers, it seems somewhat misplaced in the context of home testing, where potential users need simply to purchase a test kit to show that they have made a decision about HIV testing.

Discussion

Although HIV home testing is controversial, UNAIDS suggests that it could be a partial solution in parts of the world where there are great numbers of people living with HIV who do not know their status.[16] Home testing can be an effective way of getting more people tested more regularly and on to treatment. It has the advantages of convenience, speed, privacy and anonymity, and can therefore help to break down some of the barriers that stand in the way of people getting tested. Some of the reasons people have given for not testing for HIV include privacy and confidentiality concerns, inconvenience, a dislike of counselling, not wanting to go to a clinic, and a lack of transportation to go to clinics.[17-20]

The message that South Africa wants to get out is that we all need to know our HIV status. To this end the country has embarked on several initiatives. Statistics suggest that strategies such as the national HCT campaign have been successful in ensuring that a greater number of South Africans are tested for HIV. Arguably, a large number of the population still do not know their HIV status. The availability of HIV home testing may ensure that these individuals get tested and know their HIV status.

Surveys on home collection kits for HIV testing in the USA demonstrated that they were highly acceptable among an estimated 175 000 customers in the first year of use. Ninety-five per cent of this group collected testable specimens, while 97% of them subsequently called to learn their results.[21] Most users who responded to an associated survey were white men between 25 and 34 years old. About 60% of users and 49% of the 0.9% who tested positive had never been tested before.[22] In another study, which evaluated bimonthly testing on 241 high-risk individuals, including men who have sex with men, injecting drug users, and women at heterosexual risk, 90 - 96% of expected samples were received by the laboratory and 95% of users had test results disclosed over the telephone.[23]

A form of home-based testing for HIV, as part of a wider effort to identify and therefore treat more HIV-infected individuals in resource-constrained settings, is showing early signs of success. In resource-limited settings, home testing currently means door-to-door implementation of rapid tests by lay counsellors or community health workers. Counsellors administer varying combinations of rapid tests that can be developed in a client's home within 20 minutes, allowing receipt of results at the same visit. Other approaches involve the home delivery of HIV test results that have been developed in clinical settings. Several studies have illustrated the feasibility and acceptability of home-based testing as a strategy for expanding access to HIV testing. For example, a Ugandan

study that compared four HIV testing strategies: stand-alone VCT, hospital-based PICT, home-based PICT, and household member home based testing, found that although hospital-based PICT was associated with the highest proportion of individuals receiving a diagnosis of HIV infection, home-based and household member home-based testing reached the greatest proportion of previously untested adults.[24] Similarly, in a randomised, controlled trial conducted in Zambia, which offered participants the option of testing in a clinic or an alternative location, 84% chose home as the venue for testing.[25] And in Malawi, household members in the lowest-income quartile were found to be significantly less likely to have ever used facility-based HIV testing than the rest of the population, but 70% were more likely to use the home-based rapid testing programme.[26]

Recently, South Africa's National Health Act (No. 61 of 2003) was amended to allow non-healthcare workers, such as HIV lay counsellors, also to withdraw blood via finger-prick for HIV testing.[27] The rationale for the new regulations is seemingly to address the critical shortage of healthcare workers and to expand access to HIV testing, in light of the country's HCT campaign and NSP. One could therefore argue that if properly trained non-healthcare workers can test for HIV, the same could and perhaps should hold for legally competent adults under a home testing system. People can be trained to properly draw and store their blood for testing in the same way that non- healthcare workers are. In this way, HIV home testing can also make a contribution to addressing the existing problems of staff and equipment shortages, which can have the effect of disrupting the delivery of HCT services.

Conclusion

Arguably, current strategies that rely on facility-based testing are inadequate for the goal of ensuring universal HIV identification and treatment. This demands consideration of alternative methods such as HIV home testing. I have tried to show that some of the reasons for discouraging HIV home testing may not be sufficiently justified. I suggest that the concerns about HIV home testing need not act as impediments to making available safe and reliable test kits to, at least, a limited class of individuals, namely legally competent adults. Appropriate education on, for example, the proper use, nature, implications and limitations of the test as well as the offer of alternative modes of counselling are means that can facilitate informed decision making by potential users. Many of the concerns about HIV home testing can be avoided through careful planning, implementation, monitoring and regulation of the system. Pharmacists can play an important role in home testing systems. This includes the sale of safe, appropriate and reliable test kits that have received approval from appropriate authorities and comply with the regulatory requirements of the country.

However, although theoretical arguments can be made in support of HIV home testing, its introduction should be based on sound scientific data, a thorough risk-benefit analysis, its cost-effectiveness, and consultation with prospective users, around acceptability and cost in particular. The translation of US testing kits to the South African context requires consideration of several issues. First, an appropriate test must detect HIV subtypes and clades that are prevalent in the region. Second, the test should be easy, safe and quick to use, and simple to interpret. Finally, expanding HIV testing through home testing is only beneficial to individuals and the public at large if testing is linked to effective prevention, medical care and psychosocial support. Introducing home testing therefore requires that efficient measures are in place to ensure clinical care and support services for those who are identified as infected at home.

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