ISSUES IN PUBLIC HEALTH

Home self-testing for HIV: AIDS exceptionalism gone wrong

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Self-tests for HIV in South Africa are currently unregulated. Gaps in law and policy have created a legal loophole where such tests could effectively be sold in supermarkets, but not in pharmacies. At the same time, South Africa lacks an effective regulating mechanism for diagnostic tests, which brings the quality and reliability of all self-tests into question. The authors argue for greater access to, and availability of, quality HIV self-tests. This strategy will encourage regular HIV testing, allay fears about stigma and confidentiality when testing in public facilities, and decrease the costs associated with traditional voluntary counselling and testing, and is likely to lead to earlier diagnosis and treatment of HIV.

The South African Medical Association (SAMA) recently warned the public against using HIV self-testing kits. SAMA chairman Norman Mabasa noted that it was 'risky' for individuals to test themselves 'unmonitored' and that it might lead to devastated patients or suicide.[1-3] These warnings were subsequently echoed by members of the national Department of Health and the Treatment Action Campaign.[4] Objections included questions about the accuracy of the tests, lack of support systems and pre- and post-test counselling, the inability to always be able to confirm the results by a second test, and the dangers of misinterpretation of the results.[1,2,4] SAMA expressed similar objections in 2005 when the supermarket chain store Pick 'n Pay explored selling self-testing kits for HIV at its outlets.[5] The Pick 'n Pay launch was subsequently cancelled.[6] Yet, during that time, HIV self-tests were available over the counter (OTC) from a number of pharmacies at prices that ranged from R40 to R60 per test.

A number of other OTC self-tests are available from the Dis-Chem pharmacy chain (Table I), while some of these were also available at the Clicks pharmacy chain and other local pharmacies. Neither Clicks nor Dis-Chem pharmacy chains stocked HIV self-tests at the time of writing, but the extent to which these are currently provided by community pharmacies is unknown. The objections that SAMA raised against HIV self-tests could apply equally to other self-tests, yet the distribution of such tests is not regulated. Other diagnoses may be as devastating, or might have been in the past. A diagnosis of type 1 diabetes, for instance, was a certain death sentence before there was widespread access to insulin. Such access is not yet universal. Pregnancy testing might also be considered to pose risks, in the absence of access to suitable professional advice. Cancer remains a dreaded diagnosis, and there are serious ethical concerns surrounding testing for 'recreational' drugs.

Table I. Self-tests (price in parentheses) available from Dis-Chem pharmacy without a prescription in 2009

- Pregnancy test (R26)
- Prostate cancer test (R44)
- Ovulation test (R94)
- Test for five separate 'recreational' drugs (R73)
- Breathalysers for alcohol (R415)

What is it about HIV/AIDS in 2010 that encourages medical, ethics and activist bodies to respond to HIV self-diagnosis with such alarm and conservatism?

HIV testing models

The term 'AIDS exceptionalism' was coined in the early 1990s to describe an approach to the AIDS epidemic that was explicitly located within a human rights and bioethics framework.[7-11] This approach to HIV/AIDS led to a novel methodology in the diagnosis of HIV: voluntary counselling and testing (VCT). VCT includes pre- and post-test counselling, express and informed consent that an HIV test would be conducted on the patient, and assurances of the confidentiality of the test result.[12]

With the advent of highly active antiretroviral treatment and subsequent increased access to such treatment, a number of authors started questioning the ongoing relevance and appropriateness of 'AIDS exceptionalism'. Proponents of the 'normalisation of AIDS' argue that it will decrease the stigma associated with the epidemic, remove barriers to testing, increase access to treatment, and change societal perceptions of HIV/AIDS.[11,13-15] There was a call for the rapid scale-up of HIV testing after the WHO/UNAIDS 3x5 initiative (treating 3 million people by 2005) was launched in 2003.[16-18] After substantial controversy and debate, the WHO/UNAIDS-endorsed 'provider-initiated testing and counselling' (PITC) model was introduced to scale up the number of people who know their HIV status. The PITC approach moves away from VCT by emphasising the health care provider's role in recommending an HIV test to patients and providing 'pre-test information' (not counselling). An HIV test would generally be performed unless the patient declines.[19] South Africa's National Strategic Plan and various authors recommend this approach.[20,21] A change to current testing practices, that has been termed HIV counselling and testing (HCT), was introduced in the 2010 guidelines, but no policy has been passed.[22,23]

New or alternative approaches to HIV testing include: (*i*) models that make subtle changes to the traditional VCT model, such as mobile VCT centres, routine offer of VCT,[24] home-based VCT;[25] (*ii*) providing monetary or other incentives to individuals to test;[26] (*iii*) home-based HIV testing where the individual sends a dry-spot test to a laboratory and the results are relayed telephonically and anonymously;[27] (*iv*) self-testing;[27,28] and (*v*) mandatory testing during pregnancy[29] or for deployment of soldiers to conflict areas.[30] The

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majority of these testing models involve a third party (a counsellor, nurse or physician) and make it near-impossible for a person to test for HIV without counselling.

State of HIV testing in South Africa

HIV testing has escalated dramatically in South Africa over the last few years, this escalation driven by the Department of Health, non-governmental and donor programmes, and the insurance industry. The 2008 HSRC Household Survey showed a significant increase in the number of people who knew their HIV status.[31] In the 2002 HSRC survey, only 21.4% of people over the age of 15 years had had an HIV test in their lifetime, compared with 30.5% in 2005, and 50.8% in 2008. Almost a quarter (24.7%) of people aged 15 - 49 years had had an HIV test in the preceding 12 months in 2008. The 2008 survey highlighted once again the important gender differences in HIV testing: significantly more women (28.7%) received an HIV test in the last 12 months and knew their results than men (19.8%).[31] The survey encouraged further initiatives to increase uptake of testing.

Current legal and policy analysis

It is clear that HIV testing needs to be expanded in South Africa, and that people should regularly retest. Self-testing for HIV could aid this process. Would HIV self-tests be possible under current South African law and policy?

Legal considerations

Self-tests for HIV should fall under the definition of a 'medical device' in the Medicines and Related Substances Control Act (Act 101 of 1965, as amended) and should be regulated by this Act. However, no mechanism for the registration of medical devices currently exists. Some medicated devices (such as drug-impregnated stents) have been registered as 'medicines', but diagnostic tests remain unregulated. The Medicines and Related Substances Amendment Act (Act 72 of 2008) attempted to remedy this situation by simply replacing the term 'medicine' throughout the Act with the term 'product, medical device or IVD (*in vitro* diagnostic)'. This Act has not yet been promulgated. The practicality of applying the same registration process for medicines to all medical devices, which range from large-scale imaging systems to disposable test kits, is questionable. There is currently no restriction on where such diagnostic tests may be sold or to whom. The only legally binding restriction on the distribution of self-testing HIV kits is provided by the Good Pharmacy Practice (GPP) standards issued by the South African Pharmacy Council. These are discussed below.

The National Health Act (Act 61 of 2003) will replace the Human Tissue Act (Act 65 of 1983) but has not yet been brought into effect in its entirety. Section 68(1)(h) of the Act makes provision for the Minister of Health to enact regulations on 'the withdrawal of blood from living persons and the preservation, testing, processing, supply or disposal of withdrawn or imported blood'. Section 68 was brought into effect on 17 May 2010;[32] the accompanying regulations[33] enabled persons who are not health care providers, but who had received at least three hours of training at a health establishment, to withdraw a 'small quantity of capillary blood sufficient for testing'. Although this enables lay counsellors to be used in HIV testing, it does not preclude patients, such as diabetics, from withdrawing their own capillary blood using suitable equipment.

Policy

The Department of Health published the National Policy on Testing for HIV in 2000,[34] which provides for the conditions under which HIV tests can be conducted in health care facilities, and is based on the traditional VCT model. It is silent on self-tests. South Africa's national AIDS policy – the National Strategic Plan 2007 - 2011 – provides new directions for HIV testing in South Africa; it tasks the Department of Health with development of 'new strategies for the provision of counselling and testing outside of health facilities'.[21] Although the 2010 clinical guidelines make reference to an 'HCT policy', no such policy has been issued. A new guideline currently before the South African National AIDS Council (SANAC) is intended to guide practitioners on HIV testing, but current drafts suggest conventional approaches to testing and counselling processes and have also not been finalised.[35]

Guidelines

The minimum conditions for screening and testing by pharmacies are provided in the GPP standards issued by the South African Pharmacy Council.[36] Section 2.13.5.8(h) of the GPP is unequivocal that '[p]harmacists must not sell HIV tests for patients to perform at home'.[36] This injunction does not apply to any other monitoring tests. The GPP notes that the Medicines Control Council does not register HIV tests, and it recommends that these tests should only be purchased from 'reputable companies' and when such tests had been registered 'in the country of origin'.

The Health Professions Council of South Africa guidelines on 'The management of patients with HIV infection or AIDS' mention self-testing in relation to potential abuse of such tests. This document advises that people who want to utilise self-tests should enquire from their doctor on their reliability and safety. The guidelines make it clear that new forms of testing 'should only be adopted if it conforms with the guidelines' – thus effectively endorsing existing health care professional-controlled methods such as VCT.

Arguments against self-testing for HIV

A number of arguments have been levelled against self-testing; they are briefly discussed below.

There is increased risk of unmanaged anxiety, with potential for suicide

The risk certainly exists that the user of a self-test may be traumatised by the test result; yet the same holds true for other conditions, such as pregnancy and cancer, that can be diagnosed by currently available self-tests. Pregnancy is a sexually transmitted condition with profound and lifelong implications that may lead to stigma and suicide. There is no move to halt the distribution of these tests (widely available in supermarkets), as weighing the benefits of knowing one's pregnancy status against possible social harms seems relatively easy. Merson and colleagues point out that, although suicide and suicidal ideation can occur after a positive HIV diagnosis, the available evidence shows that suicide only really becomes a concern when AIDS-related symptoms develop.[27]

Counselling is a vital component of HIV tests and is bypassed by self-testing

Our own experience – from undergoing counselling personally, providing it and/or running programmes that provide this service – is that the quality and applicability of counselling in South Africa is extremely variable. At its best, counselling provides information, manages anxiety, and refers people to appropriate care. At worst, it is culturally inappropriate, increases anxiety and misinformation, and leaves patients devastated and disempowered, with no link to

health or other follow-up systems. While the potential benefits of counselling are acknowledged, it should never constitute a barrier to people who want to ascertain their HIV status, but do not want to be counselled.

Testing could be coerced in a home environment

Risk of coercion (forced testing) arises with a number of self-tests, including pregnancy and drug tests. We are not aware of any available data on the incidence of such coercive testing in South Africa. HIV self-tests might have been available from some outlets, and no reports of abuse of these tests have appeared. South Africa has an extensive HIV-related legal framework in place. Legislation such as the Employment Equity Act and the National Health Act, as well as common law, should provide ample protection against potential abuse. Indeed, various authors have pointed out that potentially beneficial technology should not be prohibited because there is a chance that it could be abused.[14,37]

Accuracy of test

Opposition against self-testing has relied heavily on the claim that self-tests could be inaccurate and should therefore not be available to the public. The Food and Drug Administration (FDA) in the USA approved the first HIV self-testing kit in 1996.[25] Diagnostic testing technology has improved since the late 1990s. Nonetheless, South Africa lacks an effective regulating mechanism for all diagnostic tests – not just HIV tests. This legal loophole is one more reason to ensure that the appropriate frameworks be put into place so that all diagnostic tests, including self-tests, are thoroughly tested, approved and appropriately regulated.

In summary, the arguments against self-testing are largely based on vague fears with little or no evidence to support them. It would seem sensible to provide increased access to HIV testing in a facilitatory way, encouraging people to access care in a way that suits them, rather than based on a model that encourages unnecessary 'AIDS exceptionalism'[38] and fear-mongering. Indeed, self-testing may reach groups that have been traditionally hard to reach with general public health campaigns,[39] and would be in line with the spirit of the Patients Rights Charter and the National Health Act, that both encourage people to take responsibility for their own health.

Recommendations

We believe that self-testing should be made widely available in South Africa, and offer the following recommendations to this end:

- The current legal and policy framework should be amended to include specific provisions on self-testing kits and to remove all provisions that would prohibit their distribution. Once the South African Health Products Regulatory Authority is in place, a suitable regulatory system for all diagnostic tests, including self-tests for HIV, needs to be created.
- The information sheet in a self-testing kit should contain detailed but simple information on HIV testing with an emphasis on explaining the window period and the importance of confirming a positive HIV result at a clinic or hospital where appropriate HIV management could be offered.
- Self-testing kits should clearly display the accuracy of the test and emphasise the importance, in unambiguous language, of the need for a confirmatory test of a positive result.
- The information sheet in the testing kits should recommend that the user contact a toll-free helpline for counselling and assistance when taking the test. Existing telephone helplines (such as the National AIDS Helpline and LifeLine) should expand their services to include counsellors who have been trained to counsel people who conduct home tests, and can make the necessary referrals.
- Clear warnings should be displayed on the pack that it is illegal to test other people for HIV, while providing links to legal support and advice organisations.

Conclusion

The sentiments expressed by the medical establishment, activists and the Department of Health seem poorly thought through, especially when measured against existing practice in areas other than HIV. At present, it would seem that there is no legal impediment to supermarkets selling HIV self-testing kits, but that the GPP prohibits the sale of such tests only in pharmacies, notwithstanding which there is no mechanism in place to regulate the quality and reliability of self-tests; this situation should be addressed urgently.

We believe that the availability of accurate home-based tests will increase access to HIV testing – especially for individuals who have fears about stigma and confidentiality when testing in public facilities – will remove some of the burden of the 'worried well' from the public and private health system, and will encourage regular testing within the general population. It is foreseeable that self-testing would lead to earlier diagnosis of HIV status and earlier enrolment into treatment, and decrease the costs associated with traditional VCT.[38] South Africa has reached a point in its AIDS epidemic where individuals should be able to decide when and where they would like to test for HIV, and do so without having to involve anyone else.

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MEDICINE AND THE LAW

Standards for the reporting of sex/sexual activity of minors in a research context

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While there are no specific protocols for dealing with reports of sexual abuse of children, the Criminal Law (Sexual Offences and Related Matters) Amendment Act of 2007 (Act No. 32 of 2007) clearly stipulates that, in the event of a report of sexual abuse by a child or any other person of the abuse of a child, the relevant person has the legal (statutory) obligation to report such abuse to the police; and that it replaces previous legislation where reporting could be done to a social worker or the police. According to the Child Advocate, a disclosure by a child (specific child, specific offender) is sufficient to require such reporting.

Given this statutory requirement, research with children that focuses on children's sexuality and reproductive health is likely to encounter instances of abuse of children. According to the Act, a child is any person below the age of 18; but with reference to Sections 15 and 16 of the Act, it refers also or specifically refers to any person below the age of 16. In this report, all ages up to 17 are referenced as children. To adequately address the response of this requirement within a research context, where the involvement of law enforcement can easily jeopardise the research, the following standard operating practice is recommended:

1. Any child of 17 years or younger who reports abuse (as defined in the Act), or on whose behalf abuse is reported by a peer, care

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