Self-testing without counselling

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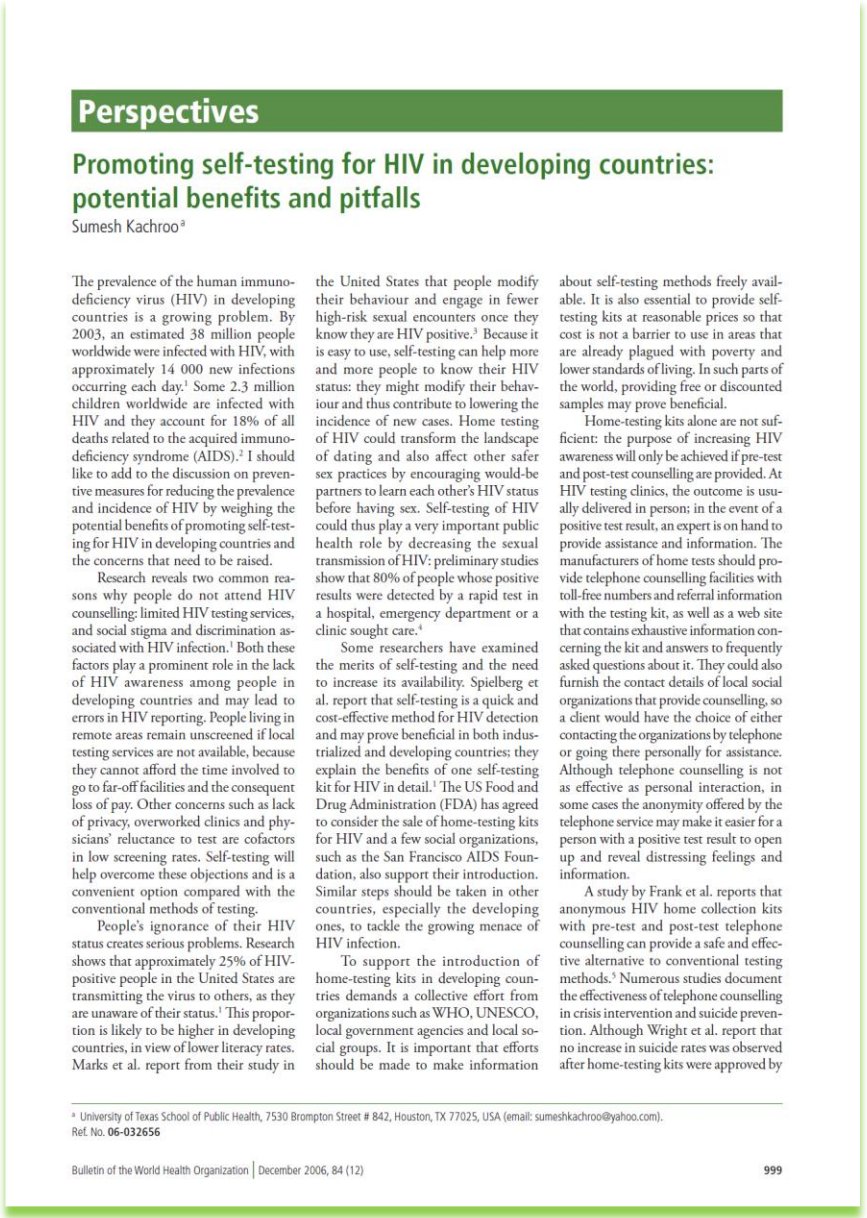
Not a new issue …

"Home testing may not provide the final solution, and a more comprehensive HIV prevention strategy will be required; however, it may prove an effective tool to increase social awareness of HIV when used hand-in-hand with voluntary counselling and testing."



Perspectives

Promoting self-testing for HIV in developing countries: potential benefits and pitfalls

Sumesh Kachroo[a]

The prevalence of the human immunodeficiency virus (HIV) in developing countries is a growing problem. By 2003, an estimated 38 million people worldwide were infected with HIV, with approximately 14 000 new infections occurring each day.[1] Some 2.3 million children worldwide are infected with HIV and they account for 18% of all deaths related to the acquired immunodeficiency syndrome (AIDS).[2] I should like to add to the discussion on preventive measures for reducing the prevalence and incidence of HIV by weighing the potential benefits of promoting self-testing for HIV in developing countries and the concerns that need to be raised.

Research reveals two common reasons why people do not attend HIV counselling: limited HIV testing services, and social stigma and discrimination associated with HIV infection.[1] Both these factors play a prominent role in the lack of HIV awareness among people in developing countries and may lead to errors in HIV reporting. People living in remote areas remain unscreened if local testing services are not available, because they cannot afford the time involved to go to far-off facilities and the consequent loss of pay. Other concerns such as lack of privacy, overworked clinics and physicians' reluctance to test are cofactors in low screening rates. Self-testing will help overcome these objections and is a convenient option compared with the conventional methods of testing.

People's ignorance of their HIV status creates serious problems. Research shows that approximately 25% of HIV-positive people in the United States are transmitting the virus to others, as they are unaware of their status.[1] This proportion is likely to be higher in developing countries, in view of lower literacy rates. Marks et al. report from their study in the United States that people modify their behaviour and engage in fewer high-risk sexual encounters once they know they are HIV positive.[3] Because it is easy to use, self-testing can help more and more people to know their HIV status: they might modify their behaviour and thus contribute to lowering the incidence of new cases. Home testing of HIV could transform the landscape of dating and also affect other safer sex practices by encouraging would-be partners to learn each other's HIV status before having sex. Self-testing of HIV could thus play a very important public health role by decreasing the sexual transmission of HIV: preliminary studies show that 80% of people whose positive results were detected by a rapid test in a hospital, emergency department or a clinic sought care.[4]

Some researchers have examined the merits of self-testing and the need to increase its availability. Spielberg et al. report that self-testing is a quick and cost-effective method for HIV detection and may prove beneficial in both industrialized and developing countries; they explain the benefits of one self-testing kit for HIV in detail.[1] The US Food and Drug Administration (FDA) has agreed to consider the sale of home-testing kits for HIV and a few social organizations, such as the San Francisco AIDS Foundation, also support their introduction. Similar steps should be taken in other countries, especially the developing ones, to tackle the growing menace of HIV infection.

To support the introduction of home-testing kits in developing countries demands a collective effort from organizations such as WHO, UNESCO, local government agencies and local social groups. It is important that efforts should be made to make information about self-testing methods freely available. It is also essential to provide self-testing kits at reasonable prices so that cost is not a barrier to use in areas that are already plagued with poverty and lower standards of living. In such parts of the world, providing free or discounted samples may prove beneficial.

Home-testing kits alone are not sufficient: the purpose of increasing HIV awareness will only be achieved if pre-test and post-test counselling are provided. At HIV testing clinics, the outcome is usually delivered in person; in the event of a positive test result, an expert is on hand to provide assistance and information. The manufacturers of home tests should provide telephone counselling facilities with toll-free numbers and referral information with the testing kit, as well as a web site that contains exhaustive information concerning the kit and answers to frequently asked questions about it. They could also furnish the contact details of local social organizations that provide counselling, so a client would have the choice of either contacting the organizations by telephone or going there personally for assistance. Although telephone counselling is not as effective as personal interaction, in some cases the anonymity offered by the telephone service may make it easier for a person with a positive test result to open up and reveal distressing feelings and information.

A study by Frank et al. reports that anonymous HIV home collection kits with pre-test and post-test telephone counselling can provide a safe and effective alternative to conventional testing methods.[5] Numerous studies document the effectiveness of telephone counselling in crisis intervention and suicide prevention. Although Wright et al. report that no increase in suicide rates was observed after home-testing kits were approved by

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Ref. No. **06-032656**

REPORT ON THE FIRST INTERNATIONAL SYMPOSIUM ON SELF-TESTING FOR HIV

THE LEGAL, ETHICAL, GENDER, HUMAN RIGHTS AND PUBLIC HEALTH IMPLICATIONS OF HIV SELF-TESTING SCALE-UP

8-9 April 2013
Brocher Foundation
Geneva, Switzerland

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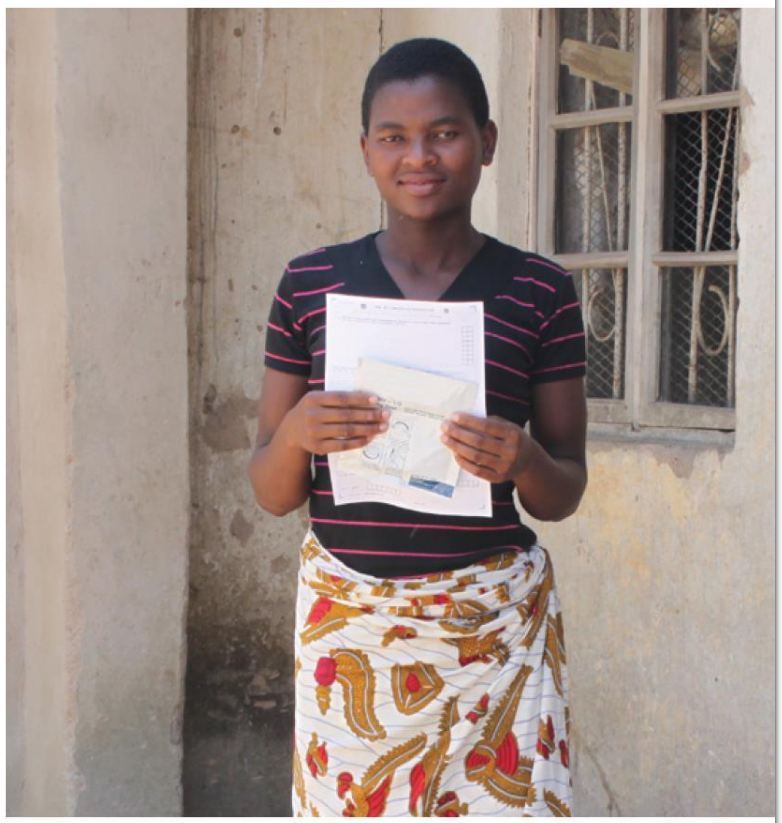
A short technical update on self-testing for HIV



World Health Organization UNAIDS

REPORT ON THE FIRST INTERNATIONAL SYMPOSIUM ON SELF-TESTING FOR HIV: THE LEGAL, ETHICAL, GENDER, HUMAN RIGHTS AND PUBLIC- HEALTH IMPLICATIONS OF HIV SELF-TESTING SCALE-UP

Baggaley R[1], Corbett E[2], Marum E[3], Davyduke T[4], Johnson C[1], Sigurdson J[5], MacPherson P[4], Ncube B[6], Taegtmeyer M[4]

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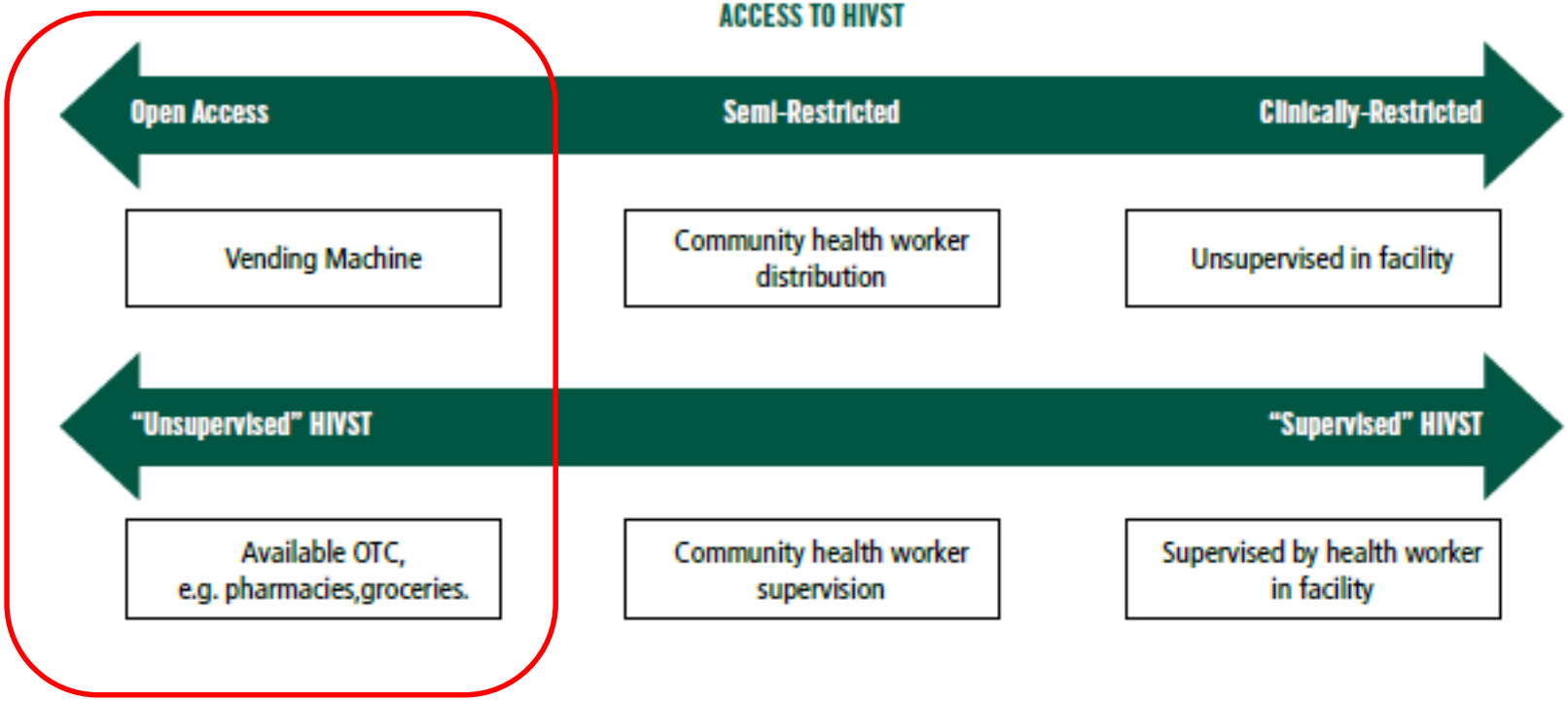

What's the concern?

- **There is increased risk of unmanaged anxiety, with potential for suicide**
  "SAMA chairman ….noted that it was 'risky' for individuals to test themselves 'unmonitored' and that it might lead to devastated patients or suicide".
- **Counselling is a vital component of HIV tests and is bypassed by self-testing**
- **Testing could be coerced in a home environment**
- **Accuracy of test**

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ISSUES IN PUBLIC HEALTH

Home self-testing for HIV: AIDS exceptionalism gone wrong

Marlise Richter, W D Francois Venter, Andy Gray

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.[7-9] 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.[10]

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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Inconsistency

- There are a wide range of self-tests currently available in pharmacies and supermarkets in SA, including tests for pregnancy, prostate cancer, ovulation, recreational drugs and breathalysers for alcohol. **Few objections have been raised against the availability of these tests, and their distribution is not regulated.**

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Enabling HIV self-testing in South Africa

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In a South African context, we consider the implications of the United States Food and Drug Administration's recent approval of the OraQuick HIV self-testing kit. We argue that current law and policy inhibit the roll-out of accurate and well-regulated self-testing kits, and create a loophole for sale in supermarkets, but not pharmacies.

S Afr J HIV Med 2012;13(4):186-187. DOI:10.7196/SAJHIVMED.858

In July 2012, the Food and Drug Administration (FDA) approved the OraQuick test (OraSure Technologies) as the first HIV self-testing kit in the USA.[1] This over-the-counter test, retailing at approximately US$35 - 40 (R245 - 280), uses saliva from a mouth swab and provides a result within 20 - 40 mins. OraSure has established a consumer support centre that provides telephonic support and referrals.[2] In a recent study of New York-based men who have sex with men (MSM) who were provided with the self-testing kit, few experienced problems performing the test.[3] Studies by the Integration of TB in Education and Care for HIV/AIDS (iTEACH) in rural KwaZulu-Natal, South Africa (SA), are showing equally promising results (K Dong, personal communication). It would seem that, with appropriate support, self-testing is poised to revolutionise HIV-testing.

SA has made immense strides in improving HIV testing coverage, at least partly owing to direct intervention by the Minister of Health.[4] However, average CD4 counts at initiation of HIV treatment remain low, suggesting that late diagnosis may still be a problem for a sizeable proportion of the population. New, more convenient ways to test for HIV may increase the proportion of individuals who know their HIV status, and help to identify infected individuals earlier in the course of disease. A recent *Lancet* editorial notes: 'Ironically, the lack of mandatory counselling with OraQuick may help decrease the stigma around testing'.[5]

Previously, we examined the arguments against self-testing and showed that critics' objections to its roll-out in SA were based largely on vague fears with little supporting evidence.[6] Similar conclusions in support of self-testing have been drawn by others.[7,8] There are a wide range of self-tests currently available in pharmacies and supermarkets in SA, including tests for pregnancy, prostate cancer, ovulation, recreational drugs and breathalysers for alcohol. Few objections have been raised against the availability of these tests, and their distribution is not regulated. We have argued that self-testing in SA may have an enormous positive effect on HIV testing uptake and early diagnosis. Self-testing could extend to groups that have been traditionally hard to reach with general public health campaigns, and would be in line with the spirit of the Patients' Rights Charter and the National Health Act, urging people to take responsibility for their own health.[6]

Yet, SA's legal and policy frameworks do not facilitate the dissemination of HIV self-tests. Self-tests are classified as 'medical devices' under the Medicines and Related Substances Control Act (Act no. 101 of 1965, as amended), but there is no regulatory system in place yet for medical devices. This means, for example, that the manufacturers of the OraQuick test would be able to market it in SA – as long as the kit, ironically, is not available in pharmacies. 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.[9] The 4th edition of the GPP, last updated in 2010, prevents pharmacists from selling the test or administering it in a pharmacy. Section 2.13.5.5 of the GPP states that 'only rapid tests which use a blood sample may be performed in a pharmacy'. Section 2.13.5.8(h) adds that 'pharmacists must not sell HIV tests for patients to perform at home.' Interestingly, this restriction does not apply to any other tests. Nor does the GPP apply to general supermarkets or corner cafes, creating a loophole for distribution. While the

Children – a particular challenge

- " ….simply offering self-HIV tests to all children aged >12 years would not be lawful, unless it could be shown that it was in their best interests and that counselling was provided."

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Is it lawful to offer HIV self-testing to children in South Africa?

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Health-facility-based HIV counselling and testing does not capture all children and adolescents who are at risk of HIV infection. Self-testing involves conducting an HIV test at home or in any other convenient space without the involvement of a third party. It is increasingly being argued that it should be incorporated into national HIV-prevention programmes as one of a range of HIV counselling and testing approaches. Although this model of HIV testing is being seen as a new way of reaching under-tested populations, no studies have been conducted on offering it to children. HIV self-tests are now available in South Africa and are sold without the purchaser having to be a certain age. Nevertheless, all HIV testing in children must comply with the norms set out in the Children's Act (2005). Here we explore whether offering self-testing to children would be lawful, by outlining the four legal norms that must be met and applying them to self-HIV testing. We conclude that, although children above the age of 12 years could consent to such a test, there would be two potential obstacles. Firstly, it would have to be shown that using the test is in their best interests. This may be difficult given the potential negative consequences that could flow from testing without support and the availability of other testing services. Secondly, there would need to be a way for children to access pre- and post-test counselling or they would have to be advised that they will have expressly to waive this right. The tests are more likely to be lawful for a small sub-set of older children if: (*i*) it assists them with HIV-prevention strategies; (*ii*) they will be able to access treatment, care and support, even though they have tested outside of a health facility; and (*iii*) psychosocial support services are made available to them via the internet or cell phones.

S Afr J HIV Med 2013;14(4):151-154. DOI:10.7196/SAJHIVMED.987

Globally, in 2010, 3.4 million children aged <15 years were HIV-positive, 90% of whom were living in sub-Saharan Africa.[1] In 2011, UNAIDS estimated that in South Africa (SA) alone there were about 460 000 children aged 0 – 14 years living with HIV. Health-facility-based HIV counselling and testing (HCT) does not capture all children and adolescents who are at risk of HIV infection.[2,3] The large number of children not treated suggests that there are still relatively low rates of testing among children.[4] Children are either being missed by the prevention of mother-to-child transmission of HIV (PMTCT) services, are surviving past two years of age without being tested, or are infected after birth through child abuse or health-service-acquired infection. In addition, children aged >12 years may be at increased risk because of their own sexual activity.[5,6] Similarly, rates of testing among adolescents are particularly low, especially among young males, despite this being an at-risk population.[6] This highlights the need for new, targeted, innovative, age-appropriate counselling and testing services for children and adolescents.[7,8]

Low uptake of HIV testing is attributed to both supply and demand factors. On the supply side, key factors include inconvenient clinic hours, the inaccessibility of health facilities and the high cost of travelling to clinics.[9,11] In terms of demand, even if testing services are available, these do not always translate into willingness to test.[12] Research has shown that deep-seated concerns regarding stigma, discrimination and the fear of positive results act as barriers to increased uptake of HIV-testing services in high HIV prevalence settings.[13]

HIV self-testing (HST) refers to the performance of a simple saliva or blood-based test similar to a pregnancy test in the privacy of a home or in any other convenient space without the involvement of a third party.[14,15] Richter *et al.*[16] point to four potential benefits of such testing; it could: encourage regular HIV testing, allay fears of stigma and possible breaches of confidentiality, decrease the overall costs of HIV testing through removing the need for face-to-face counselling, and facilitate earlier diagnosis and access to treatment. Based on increasing evidence from feasibility and acceptability studies, activists and public health policy-makers have argued that HST should be incorporated into national HIV-prevention programmes as one of a range of community-based HCT approaches.[17,18] Community-based HCT models such as home-based and mobile testing have significantly improved testing uptake and have reached higher rates of first-time testers in sub-Saharan Africa.[19-21]

HIV self-tests are now available in SA. They sell for approximately R100 at pharmacies and have a shelf-life of two years. They can also be ordered via the internet.[22] Detailed instructions are in the packaging and they generally require the user to place a drop of blood on a test strip; if a dark line develops on the strip, it indicates that the person is HIV-

AIDS and Behaviour supplement July 2014

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Volume 18, Issue 4 Supplement, July 2014

Special issue on HIV self-testing

Issue Editors: Miriam Taegtmeyer, Cheryl Johnson, Rachel Baggaley

ISSN: 1090-7165 (Print) 1573-3254 (Online)

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Original Paper
Factors Associated with Acceptability of HIV Self-Testing Among Health Care

Feedback

Key points

- The FDA-approved OraQuick In-Home HIV Test is the only HIVST kit that meets international standards. Other less rigorously evaluated diagnostics, however, are available over-the-counter or through
- With current tests, user errors are very common. Key challenges included: the lack of integrated test components, poor labeling and unclear instructions on how to perform the test and how to interpret results.
- Ethically:
  - HIV testing, has results that are arguably no more life-changing than those of other diseases and conditions, such as diabetes and pregnancy, for which self-testing is readily available and less rigorously evaluated.
  - Challenges - scaling-up testing where treatment is unavailable, increasing user autonomy without support, and increasing potential risk for coercive testing, inter-partner violence, and psycho-social distress, especially in settings with pre-existing violence and among key populations who fear accessing HIV services. Moreover, HIVST will also impact legal policies that criminalize the transmission of HIV and could alter who incurs responsibility for partner-notification and linkage to HIV services.

AIDS Behav (2014) 18:S445–S449
DOI 10.1007/s10461-014-0831-y

ORIGINAL PAPER

A Review of the Evidence of Harm from Self-Tests

Annette N. Brown · Eric W. Djimeu · Drew B. Cameron

"Despite the limitations, this review found very little evidence of any harm occurring in the practice of self-testing. Based on these findings, we recommend that HIV self-testing not be restricted based on fears of harm, but rather that as self-testing is expanded, researchers and policy makers pay particular attention to monitoring and measuring for unintended harm."

Recommendations

"To fully maximize the opportunity HIVST presents, the public health community can support the current momentum by ensuring that:

- post-market surveillance systems are developed,
- estimates of the market size and cost-effectiveness of HIVST are enhanced,
- policy and regulatory systems to ensure the quality of available HIVST kits are developed,
- systems to monitor and report social harms, and track and identify how people who self-test are linked to prevention, care and treatment services are developed, and
- Innovative methods and technologies are leveraged, such as mHealth and eHealth interventions."

Johnson C et al. Realizing the Potential for HIV Self-Testing. AIDS Behav 2014. DOI 10.1007/s10461-014-0832-x