



Southern African AIDS Trust

REPORT

REGIONAL

2014



REVIEW – MALAWI

**LEGAL ISSUES SURROUNDING
THE DISTRIBUTION OF
HIV SELF-TESTING KITS**



FOREWORD

While the focus of much of the global community may be moving on from HIV and AIDS to other issues, it cannot yet be said to be “the end of AIDS” in Africa. HIV & AIDS will continue to impact communities and public health systems in eastern and southern Africa for decades to come and both morbidity and mortality in the region will be significantly increased as HIV & AIDS influences health issues such as TB, maternal mortality, and sexual and reproductive health more broadly.

One of the key critical success factors in fulfilling the UNAIDS and global goal of zero new infections, zero deaths and zero discrimination is people knowing their own HIV sero-status and having the ability to act on the knowledge. Yet in eastern and southern Africa, despite decades of investment in HIV testing and counselling, many people still do not know their status.

Across the region there remain wide variations in data regarding the proportion of the general population who have accessed HTC. Figures for 2011¹ show Botswana at over 60% (2011), Malawi at 34%, and Zambia 15%. **Presently less than half of all Africans know their HIV status, and only 25% received an HIV test in 2012¹.** Uptake and access to HIV testing is lower among members of key population communities who, while facing a higher HIV burden, also face issues of stigma, discrimination and other barriers to access.

It is in this context that SAT believes in thinking out-of-the-box. After decades of investment more of the same is unlikely to be a game changer with regard to increasing the number of people empowered by knowledge of their own status to take action.

HIV self-testing may be just such an ‘out-of-the-box’ solution. Defined as, ‘when a test is collected, performed and interpreted in private by the individual who wants to know their HIV status’, self-testing, in combination with other new thinking on HTC opens new possibilities for reach and engagement.

To explore this possibility, SAT commissioned a multi-country legal review of national policies and legislation that frame and provide the context for thinking about HIV self-testing.

With the generous coordination from the Thomson Reuters Foundation, SAT worked with a strong team of international and Southern African legal firms to conduct a review of the laws relevant to HIV self-testing (HIVST) in their respective jurisdictions, namely Botswana, Malawi, Mozambique, South Africa, Tanzania, Zambia and Zimbabwe as well as France, the UK (England) and the USA. All work conducted by the firms (see below) was done on a pro bono basis as a contribution to global development.

The review sought to answer key contextual questions that would frame any pilot or projects that countries might choose to take up to increase numbers of the population who know their HIV status. Included were questions such as, “Is HIV self-testing legal and, if so, under what conditions?”, “What legislation governs the distribution of HIVST kits and what rules/conditions exist concerning this

¹ UNAIDS 2013; WHO 2013

distribution?” and “What are the human rights issues surrounding HIVST?” The review looked across SAT’s countries of operating but also went broader to explore the situation in the USA, France and the UK – all of which have now legalised self-testing after thorough national debates and scientific input.

In the last stages of the review SAT and the University of Witwatersrand Reproductive Health Institute hosted a Consultative Workshop in March 2014 with participants from governments, National AIDS Councils, key population groups, community organisations, WHO, medical experts and researchers. The think tank worked with the emerging review as well as with evidence from two very successful research/pilot sites in the SADC region and explored what the possibilities and practicalities of implementing self-testing might be. The think tank report may also be accessed on the SAT website above.

The issue of self-testing is not uncontroversial, and it has been known to raise strong feelings both for and against. The think tank was useful and hearing from the research sites de-bunked many of the myths about self-testing such as “it is incompatible with referring people into the health system”, or “people will not understand how to use it or how to interpret the results”. Innovators in a number of places, not least in the SADC region, have worked hard and designed and tested solutions and in some cases products to overcome these challenges.

HIV self-testing is not a magic bullet. In combination with other innovative thinking, however, it may hold the key to increasing reach of testing, opening new options for hard to reach communities, making life easier for serodiscordant couples and supporting both prevention and treatment.

We are pleased to present to you the HIVST Legal Report for Malawi. This report is intended to inform SAT and all its strategic partners about the legal framework and human rights implications relevant to HIVST in Malawi.

The summary consolidated findings for all the above mentioned countries as well as individual country reports are available at SAT on request as well as on the website,

It is our fervent hope that the findings will have a catalytic effect on dialogues on this subject and forge a way for HIV self-testing in Malawi and across the region.

Welcome to the conversation. We look forward to your feedback.

Jonathan Gunthorp



Executive Director - SAT

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SAT also wishes to thank civil society organisations and partners who attended the HIV Self-testing Consultative Workshop in March 2014 to discuss the draft legal reports, including the merits, challenges and opportunities of integrating HIV self-testing into existing community level HIV and SRHR programmes.

SAT is grateful to Wits Reproductive Health Institute for all their technical support and input during the March 2014 HIV Self-Testing Consultative Workshop.

Last but not least, we would like to thank Thomson Reuters Foundation's global pro bono service, TrustLaw, who helped coordinate the project and brokered, free of charge, the relationships between SAT and the legal firms.

DISCLAIMER

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MALAWI

MALAWI

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(VINCENT CHIKAONDA)



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1. INTRODUCTION/BACKGROUND

- 1.1 Legal issues surrounding the distribution of HIV self-testing kits.
- 1.2 Malawi, like many other countries in Africa, is experiencing the serious epidemic of HIV/AIDS. In 2001 Malawi formulated a National HIV/AIDS Policy designed to respond to the particular experiences of the country. The policy provides technical and administrative guidelines for the design, implementation and management of HIV/AIDS interventions, programmes and activities at all levels of the Malawi Society. There is however no legislation specifically to deal with issues of HIV/AIDS in Malawi. The National HIV/AIDS Policy does not have the force of law.

2. SUMMARY OF ADVICE

- 2.1 In Malawi, there is no law that regulates issues of HIV/AIDS generally, or prohibits HIV self-testing. Distribution of HIVST kits will normally be governed by the general law relating to consumers which is the Consumer Protection Act (Cap 48:10) of the Laws of Malawi. A person must consent before an HIV test is done. The results of any HIV positive test should not be disclosed to a third party without the consent of the person seeking the test. HIV positive persons should however be encouraged to notify their partners. There is no legislation that imposes criminal sanctions for reckless or intentional transmission of HIV.

3. IS HIV SELF-TESTING LEGAL AND, IF SO, UNDER WHAT CONDITIONS?

- 3.1 In Malawi, there is no law that prohibits HIV self-testing. There are no laws which prescribe conditions under which procedures and processes such as HIV self-testing must be carried out.
- 3.2 HIV self-testing is not defined legally or in policy or official guidelines. There is no technical definition or any definition of HIV self-testing kits.

4. WHAT LEGISLATION GOVERNS THE DISTRIBUTION OF HIVST KITS & WHAT RULES/ CONDITIONS EXIST CONCERNING THIS DISTRIBUTION?

- 4.1 The distribution of HIVST kits will normally be governed by the general law relating to consumers which is the Consumer Protection Act (Cap 48:10) of the Laws of Malawi. Malawi does not have laws which regulate medical devices.
- 4.2 Under section 6 of the Consumer Protection Act, a supplier or trader of technology, goods or services has the following obligations:
 - a) to take necessary and appropriate measures concerning technology, goods or services he provides for the prevention of danger;
 - b) to ensure correct ingredients, measures and weights, and give proper indication of technology, goods or services, as the case may be;
 - c) to ensure that imported technology and goods meet the Malawi Standards;
 - d) to cooperate with the Government or Local Authorities in the execution of policies relating to consumer protection;
 - e) to not supply technology, goods or services which can cause injury or harm to a consumer or the environment and which do not comply with the Malawi Standards; and
 - f) to provide consumers with true, sufficient, clear and timely information on technology, goods or services that they offer.

5. WHAT ARE THE HUMAN RIGHTS ISSUES SURROUNDING HIVST?

5.1 Human rights issues surrounding HIVST may include: (i) lack of adequate information about the nature of an HIV test, in order to make an informed decision as to whether to take the test or not; (ii) lack of adequate consideration of ethical, human rights, gender and legal issues; (iii) lack of adequate consideration of the impact of HIVST e.g effect of lack of counselling.

5.2 Does every person have a right to be tested?

5.2.1 Every person has access to health care services in Malawi which includes VCT but this is not specifically provided for in the law.

5.3 Can a person be compelled to make any disclosures concerning a positive diagnosis and, if so, in what circumstances?

5.3.1 Under the Malawi Constitution every person has a right to privacy. Further, in terms of the National AIDS Policy, voluntary counselling and testing should either be confidential or anonymous, and the results of any HIV test should not be disclosed to any third party without the consent of the person seeking testing.

5.3.2 However, the National AIDS Policy provides that HIV post-test counselling should involve strong professional efforts to encourage, persuade and support HIV positive persons to disclose their status to their partners. It also provides that in exceptional cases where a properly counselled HIV positive person refuses to disclose their status to sexual partners, health care providers are permitted to notify those partners without the consent of the source client. This appears to be an exception to the constitutional right to privacy (which is not an absolute right) perhaps on the justification of protecting the health of the partner. The constitutionality of this exception has not been tested.

5.4 Can a person be forced to take a test or compelled to have a child tested?

5.4.1 Generally, a person cannot be forced to take a test or compelled to have a child tested. However, in terms of the National Aids Policy, where a person has difficulty making an informed decision to have an HIV test, and where an HIV infection is suspected, HIV testing should be part of the diagnostic testing. HIV testing without consent is permitted in screening of pregnant women through anonymous unlinked testing for surveillance to prevent transmission from mother to child; and testing of blood, body fluids and other body tissues for transfusion and transplants.

5.4.2 With respect to children, if a medical officer has certified in writing that there is immediate risk to the health of a child, a social welfare officer or police officer may authorise an examination or treatment as may be considered necessary by the medical officer without obtaining consent of the parent or guardian, but only under any of the following circumstances:

- a) that the parent or guardian of the child or any person having authority to consent to such examination or treatment has unreasonably refused to give, or abstained from giving consent to such treatment;
- b) that the parent or guardian or the person having authority to consent to such examination or treatment is not available or cannot be found within a reasonable time; or
- c) the social welfare officer or the police officer believes on reasonable grounds that the parent or guardian or the person having authority to consent to such examination or treatment has ill-treated, neglected, abandoned, or exposed to physical, mental social or moral hazards¹ or sexually abused the child.

5.5 What is the law regarding discrimination based on a person's diagnosis with HIV?

5.5.1 The law does not allow discrimination. Under section 20 of the Malawi Constitution discrimination of persons in any form is prohibited and all persons are, under any law, guaranteed equal and effective protection against discrimination on grounds of race, colour, sex, language, religion, political or other opinion, national, ethnic or social origin, disability, property, birth or other status or condition. Although the Constitution does not specifically refer to discrimination on the basis of a person's HIV status one can argue that the words "other status or condition" may include a person's HIV status.

¹ Section 3 of the Child Care, Protection and Justice Act obliges parents or guardians to protect the child from exposure to physical, mental, social and moral hazards.

6. WHAT IS THE LIABILITY, TO THE PATIENT AND/OR THIRD PARTIES, OF A SUPPLIER IF A KIT IS FAULTY/GIVES AN INACCURATE DIAGNOSIS? IS THE ANSWER DIFFERENT IF A KIT IS SOLD RATHER THAN SUPPLIED FREE OF CHARGE?

- 6.1 Under section 41(6) of the Consumer Protection Act, a trader or supplier of technology, goods or services which causes harm or danger is liable for the damage caused and bears the expenses of withdrawing the technology, goods or services from the market. Whether or not harm or danger is caused by an inaccurate diagnosis will depend on the reaction of the user. Please note that people react differently to HIV diagnosis.
- 6.2 The Consumer Protection Act does not specifically spell out the nature of liability to a consumer. In our view liability for defective or dangerous products under the Consumer Protection Act arises under tort (negligence) or contract law. It is not a strict liability regime. Under this Act any action may be brought against any constituent of the distribution chain which sold such technology, goods or services including manufacturer, wholesaler, retailer or trader, all of whom may be severally or jointly liable. The patient and/or third parties will be entitled to indemnity for consequential injury or loss if a kit is faulty or gives an inaccurate diagnosis. It does not matter that the kit is sold or supplied free of charge.
- 6.3 Contract or tort/negligence law can be used to take out a product liability or personal injury claim outside the context of the Consumer Protection Act.

7. FURTHER ISSUES CONCERNING HIV REGARDING CONSENT, COUNSELLING, DISCLOSURE AND CONFIDENTIALITY

7.1 Must a person consent to testing (is written consent required)?

- 7.1.1 A person must consent before an HIV test is done. Written consent is not required. However as stated in paragraph 4.4 in certain instances HIV testing without consent is permitted. If an HIV test is taken without consent this may amount to a breach of the right to privacy and a person can sue for compensation.

7.2 What is the legal age to give consent and what powers do parents/guardians hold in relation to consent process?

- 7.2.1 Under the Child Care, Protection and Justice Act 2010 the legal age of majority is 16, as a child is defined as a person below the age of 16 years. The legal age to give consent may therefore be taken to be 16. However, in terms of the National Aids Policy, children aged 13 or over are entitled to access voluntary counselling and testing without the consent of a guardian or other adult.
- 7.2.2 As regards the powers which parents or guardians have in relation to the consent process, under section 23 of the Malawi Constitution, the best interests and welfare of children is the primary consideration in all decisions affecting them. Under the Child Care, Protection and Justice Act, parents or guardians are entitled to be notified consulted and to consent in relation to any examination or treatment of a child. However, if a medical officer has certified in writing that there is immediate risk to the health of a child, an examination or treatment may be authorised without obtaining consent of the parent or guardian, but only under the circumstances described above at paragraph 5.4.2.

7.3 What are the rules/norms concerning the provision of counselling to those with a positive diagnosis?

- 7.3.1 There is no legal requirement to provide counselling. In practice counselling is normally provided before and after an HIV test. In terms of the National Aids Policy, HIV post-test counselling should involve strong professional efforts to encourage, persuade and support HIV-positive persons to notify their partners. As regards pre-test counselling, the National Aids Policy provides that voluntary counselling and testing should only be carried out with informed consent of the person seeking testing, who is provided with adequate information about the nature of an HIV test, including the potential implications of a positive or negative result, in order to make an informed decision as to whether to take the test or not.
- 7.3.2 The National Aids Policy acknowledges that through pre-trial and post-test counselling carried out in a supportive environment, a person undergoing voluntary HIV counselling and testing is motivated towards positive behaviour change.

7.4 Confidentiality of test results

- 7.4.1 In terms of the National Aids Policy, voluntary counselling and testing should be confidential and anonymous. The results of any HIV-positive test should not be disclosed to a third party without the consent of the person seeking testing. However as stated in paragraph 5.3.2, in exceptional cases where a properly counselled HIV – positive person refuses to disclose their status to their sexual partners, health care providers are permitted to notify those partners without the consent of the source client.

7.5 Duties of disclosure to partner/employer/insurer

- 7.5.1 As stated in paragraph 7.4, HIV-positive persons should be encouraged to notify their partners. There is however no duty placed on them to disclose their sero status to partners, employers or insurers.

8. WHAT ARE THE CRIMINAL IMPLICATIONS OF TRANSMITTING – OR BEING RECKLESS AS TO TRANSMISSION OF – HIV?

- 8.1 There is no legislation at present that imposes criminal or civil sanctions for reckless or intentional transmission of HIV.
- 8.2 We do not think there are any loopholes in the National HIV/AIDS policy that may imply or may be interpreted to imply criminalisation of wilful transmission of HIV. As stated above in paragraph 1.1 the National HIV/AIDS policy does not have force of law.

9. FURTHER INFORMATION

- 9.1 In Malawi, there is no law that prohibits the distribution of HIV self testing kits.

10. REFERENCES

- 10.1 a) the Constitution of the Republic of Malawi.
- 10.2 b) the Consumer Protection Act (Cap 48:10).
- 10.3 c) Child care, Protection and Justice Act, 2010.
- 10.4 d) National HIV/AIDS Policy (Malawi).

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