



Southern African AIDS Trust

REPORT

REGIONAL

2014



REVIEW-TANZANIA

**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

¹ UNAIDS 2013; WHO 2013

legislation governs the distribution of HIVST kits and what rules/conditions exist concerning this 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 Tanzania. This report is intended to inform SAT and all its strategic partners about the legal framework and human rights implications relevant to HIVST in Tanzania.

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 Tanzania and across the region.

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

Jonathan Gunthorp



Executive Director - SAT

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Special thanks go to Nexus Attorneys (Tanzania) who provided pro bono legal services to undertake the review on HIV Self-Testing in Tanzania and Arnold & Porter (UK), in particular to Catherine Young for coordinating the legal review in all the participating countries.

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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REVIEW



TANZANIA

THE UNITED REPUBLIC OF TANZANIA

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CONTENT PAGE

1	INTRODUCTION/BACKGROUND	3
2	SUMMARY OF ADVICE	3
3	IS HIV SELF-TESTING LEGAL AND, IF SO, UNDER WHAT CONDITIONS?	4
4	WHAT LEGISLATION GOVERNS THE DISTRIBUTION OF HIVST KITS AND WHAT RULES/CONDITIONS EXIST CONCERNING THIS DISTRIBUTION?	4
5	WHAT ARE THE HUMAN RIGHTS ISSUES SURROUNDING HIVST?	4
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
7	FURTHER ISSUES CONCERNING HIV REGARDING CONSENT, COUNSELLING, DISCLOSURE AND CONFIDENTIALITY	6
8	WHAT ARE THE CRIMINAL IMPLICATIONS OF TRANSMITTING – OR BEING RECKLESS AS TO TRANSMISSION OF – HIV?	7
9	FURTHER INFORMATION	7
10	REFERENCES	8

1. INTRODUCTION/BACKGROUND

- 1.1 The HIV/AIDS epidemic continues to pose a challenge to all sectors in Tanzania. The epidemic has interacted with other underlying public health problems such as tuberculosis and thus it is now one of the top causes of morbidity and mortality in the country.
- 1.2 Since Tanzania declared HIV/AIDS a disaster in 1999, notable developments have been realized in the prevention, treatment, care, and support of those who are infected with and affected by the disease. In October 2004, the Government of Tanzania commenced a programme of providing the life-saving antiretroviral drugs to HIV/AIDS patients. The target is to provide treatment with antiretroviral drugs to 440,000 patients by the end of 2008. However, progress towards accomplishment of this target has been slow, partly due to inadequate identification of those eligible for treatment.
- 1.3 Available information estimates that only about 15% of Tanzanians know their HIV status. For many years, voluntary counselling and testing (VCT) at the patient's request has been the main model through which individuals learn their HIV status. This approach has been quite useful in reinforcing HIV prevention especially in healthy people, but falls short of capturing important groups such as patients who present to health care facilities with HIV-related conditions.
- 1.4 Source: Guidelines for HIV Testing and Counselling in Clinical Settings, Ministry of Health Tanzania, July 2007

2. SUMMARY OF ADVICE

- 2.1 Currently there is a global move to accelerate universal access to HIV prevention, treatment, care and support services for People Living with HIV and AIDS (PLHA). This calls for urgent scaling up of HIV testing in Tanzania using different approaches.
- 2.2 In 2008, the Parliament of the United Republic of Tanzania enacted the law that governs HIV and AIDS matters, the HIV and AIDS (Prevention and Control) Act, 2008 (the "Act"). This Act provides for: prevention, treatment, care, support and control of HIV and AIDS; promotion of public health in relation to HIV and AIDS; appropriate treatment, care and support using available resources to people living with or at risk of HIV and AIDS; and related matters.

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

- 3.1 Section 13(1) of the HIV and Aids (Prevention and Control) Act, 2008 requires individuals who want to be tested for HIV to go to authorized centers for HIV testing and HIV tests must be carried out by qualified clinical personnel. HIV self-testing kits are legal in Tanzania as long as the patient uses the test in a recognised center for the purposes of the Act. The law would, therefore, need to be amended to suit the purpose for the usage of the aforementioned kits. The amendments would have to be tabled at parliament (through lobbying an activist Member of Parliament et al)¹. The length of this process differs case by case and depends entirely on the Parliament sessions. It may take one sitting for the amendment to be approved. An MP may initiate a private motion to that regard.
- 3.2 In line with the above, Section 3 of the Act defines "**HIV testing**" to mean "**any laboratory procedure** done on an individual to determine the presence or absence of HIV infection" [emphasis added]. This definition could be wide enough to include 'rapid testing kits' if they are considered as part of the term 'laboratory procedure'. There is no legal definition for HIV self-testing nor a technical definition for an HIV self-testing kit as they are not accommodated for in the law governing HIV / AIDS issues.
- 3.3 Therefore Section 13 of the Act provides that for the purposes of facilitating HIV testing, every public HIV Testing and Counselling ("HTC") health care facility and voluntary counselling and HIV Testing Center Recognized by the National AIDS Control Programme ("NACP") shall be an HIV testing center for the purpose of this Act. The Act also provides that the Private Health Laboratory Board² may, by Order published in the Gazette, accredit any private laboratory to be an HIV testing center. However, a person shall not undergo HTC except in a center provided under Part V of the said Act. For the purposes of this section HIV testing center includes any center established in any place for the purposes of HIV testing.
- 3.4 The guidelines issued under the NACP do not address HIV self-testing but self-testing is discouraged by the Tanzanian government. The National Guidelines for the Management of HIV and AIDS states that "... all testing done outside a laboratory setting must be supervised by qualified laboratory personnel to ensure accurate and quality results". The Health and Social Welfare Ministry has cautioned the public against using the Korean HIV reagent dubbed 'SD Bioline 3.0' being distributed by unidentified people, saying the testing kit has expired. Tanzania employs two types of HIV reagents - 'Allere Determine' as the first and if one is found to be HIV positive 'Unigold' is employed to confirm the results³.
- 3.5 The government "regarded the kits just like those used to test malaria and pregnancy, only that there were being used without prior counselling by a qualified personnel as a procedure for HIV/Aids testing" demands⁴.

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

- 4.1 The relevant law in Tanzania is the HIV and Aids (Prevention and Control) Act, 2008.
- 4.2 The law does not prohibit the said kits, however in line with the Tanzania Food, Drugs and Cosmetics Act of 2003, the kits have to be approved by the Tanzania Food and Drug Authority ("TFDA") and they have to be used in an approved laboratory.
- 4.3 The TFDA's mission is to protect and promote public health by ensuring quality, safety and effectiveness of food, drugs, cosmetics and medical devices.
- 4.4 The TDFA Laboratory carries out analysis to ascertain the quality, safety and effectiveness of food, drugs, herbal drugs, cosmetics and medical devices manufactured or imported into Tanzania. The results obtained are used for decision-making. (The Tanzania Food, Drugs and cosmetics, Act No 1 of 2003 section 14 gives legal power to the TFDA Laboratory.)

5. WHAT ARE THE HUMAN RIGHTS ISSUES SURROUNDING HIVST?

5.1 Does every person have a right to be tested?

- 5.1.1 Everyone in Tanzania has the right to be tested for HIV. Section 15(1) of the Act states that "every person residing in Tanzania may on his own motion volunteer to undergo HIV testing". A pregnant woman and the man responsible for the pregnancy or spouse and every person attending a health care facility shall be counselled and offered voluntary HIV testing.

¹ Any other interested person or group can act as a lobbyist i.e the MP himself/herself or indirectly through the said person or group.

² The Private Health Laboratory Board is the Board responsible for registration, control and regulations of private health laboratories. It is established under Section 4 of the Private Health Laboratories Regulations Act, 1997 .

³ Chiwambo, Y., Public alerted on expired HIV testing kit, IPPmedia.com, 27 November 2013

⁴ Qorro, E., Tanzania: Govt Concerned Over Use of HIV Self-Test Kits, The Citizen (Dar es Salaam) 29 May 2011

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

- 5.2.1 No. it is purely voluntary save for the High Court Order.
- 5.2.2 Section 16 of the Act provides that the results of an HIV test shall be confidential and shall be released only to the person tested. However, the results of an HIV test may be released to:
 - a) in case of a child, his parent or recognized guardian;
 - b) in case of person with inability to comprehend the results, his spouse or his recognized guardian;
 - c) a spouse or a sexual partner of an HIV tested person; or
 - d) the court, if applicable

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

- 5.3.1 Section 24 of the Act provides that a person being the owner, manager or in charge of a health care facility or medical insurance provider, whether public or private, shall facilitate access to health care services to persons living with HIV and AIDS without discrimination on the basis of their status.
- 5.3.2 Section 28 of the Act stipulates further that a person shall not formulate a policy, enact any law or act in a manner that discriminates directly or by its implication persons living with HIV and AIDS, orphans or their families.
- 5.3.3 Section 29 of the Act states that any health practitioner who deals with persons living with HIV and AIDS shall provide health services without any kind of stigma or discrimination.
- 5.3.4 On stigma, Section 31 of the Act states that a person shall not stigmatize or discriminate in any manner any other person on the grounds of such other person's actual, perceived or suspected HIV and AIDS status.
- 1.1.1 And the law provides for punitive measures under Section 32, that any person who contravenes any provision under this Part commits an offence and on conviction shall be liable to a fine of not less than two million shillings or to imprisonment for a term not exceeding one year or to both.
- 1.1.2 Furthermore, Section 30 of the Act provides that any person shall not -
 - a) deny any person admission, participation into services or expel that other person from any institution;
 - b) deny or restrict any person to travel within or outside Tanzania;
 - c) deny any person employment opportunity;
 - d) deny or restrict any person to live anywhere; or
 - e) deny or restrict the right of any person to residence,
- 5.3.5 on the grounds of the person's actual, perceived or suspected HIV and AIDS status.

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

- 1.1.3 No. it is purely voluntary save for the High Court Order.
- 1.1.4 Section 15 states that every person residing in Tanzania may on his own motion volunteer to undergo HIV testing. That a child or a person with inability to comprehend the result may undergo HIV testing after a written consent of a parent or recognized guardian and that a person shall not be compelled to undergo HIV testing.
- 1.1.5 However, without prejudice to the generality of this section, no consent shall be required on HIV testing if it is (a) under an order of the Court; (b) on the donor of human organs and tissues; and (c) to sexual offenders.
- 1.1.6 On a pregnant woman and the man responsible for the pregnancy or spouse and every person attending a health care facility shall be counselled and offered voluntary HIV testing.
- 1.1.7 All health practitioners, traditional and alternative health practitioners, traditional birth attendants and any other person attending patients shall be encouraged to undergo HIV testing.
- 1.1.8 Any health practitioner who compels any person to undergo HIV testing or procures HIV testing to another person without the knowledge of that other person commits an offence. The offence is punishable by a fine of not less than two hundred thousand shillings or imprisonment for a term of not less than three months or to both such imprisonment and fine (Section 15(7); read together with Section 50 of the Act.).
- 1.1.9 Furthermore, without prejudice to the preceding subsections, a medical practitioner responsible for the treatment of a person may undertake an HIV test in respect of that person without the consent of the person if-
 - a) the person is unconscious and unable to give consent; and
 - b) the medical practitioner reasonably believes that such a test is clinically necessary or desirable in the interest of that person.

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 There is a separate entity that approves all medical and quality issues called the Tanzania Food and Drug Authority (“TFDA”). If the kits are approved by the TFDA, and regardless of whether the kits are sold or supplied free of charge, the supplier is not liable towards individuals who use the kits or third parties. The liability either way shall be against the TFDA who has approved and recommended the usage of said kits. The patient may sue the TFDA under civil proceedings (the law of tort). In line with the above Tanzania at the moment relies on the law of torts as there is no specific legislation dealing with product liability governing manufacturers’ duties to consumers.

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 Yes, according to Section 15 of the Act there must be informed consent. Informed consent means the voluntary agreement of a person to undergo or be subjected to a procedure based on full information, whether such agreement is written, conveyed verbally or indirectly expressed (Section 15 of the Act).

7.1.2 Section 15(7) makes it an offence for a health practitioner to compel a person to undergo HIV testing or procures another person to undergo HIV testing without the knowledge of that other person. The actual penalty is under section 50 as quoted below:

“Section 50: Any person, who commits any offence against the provisions of this Act shall be liable on conviction for every such offence except wherein any other section a specific penalty is provided to a fine of not less than two hundred thousand shillings or to imprisonment for a term of not less than three months or to both such imprisonment and fine”.

7.1.3 The spirit of this Act is for all procedures to be carried out under the supervision of a health practitioner and not otherwise so no sanction is provided where a lay person compels another to be tested. However, mandatory or forced testing is not permitted under Section 15(3) “A person shall not be compelled to undergo HIV testing”. Anyone who compels another to undergo HIV testing is liable on conviction for every such offence to a fine of not less than two hundred thousand shillings or to imprisonment for a term of not less than three months or to both such imprisonment and fine (Section 50 of the Act).

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 The legal age to issue consent is 18 years old.

7.2.2 In accordance with Section 15, a child or a person with inability to comprehend the result may undergo HIV testing after a written consent of a parent or recognized guardian.

7.2.3 As per section 16, the results of an HIV test shall be confidential and shall be released only to the person tested. However, the results of an HIV test may be released to (a) in case of a child, his parent or recognized guardian; or (b) in case of person with inability to comprehend the results, his spouse or his recognized guardian.

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

7.3.1 Sections 13 and 14 of the Act stipulate that for the purposes of facilitating HIV testing, every public HTC health care facility and voluntary counselling centre recognized by the NACP shall be an HIV testing centre for the purpose of this Act. Therefore the Private Health Laboratory Board may, by Order publish in the Gazette, accredit any private laboratory to be an HIV testing centre.

7.3.2 Pre and post-test counselling for the patient is a mandatory condition for the provision of testing in HIV testing centres. During the pre-test counselling session, the client is prepared for the test by a Counsellor to receive pertinent information on HIV/AIDS and assess his/her readiness to take the test. The client is also given the opportunity to consider the meaning and impact of the test results on his/her life. Post-test counselling takes place after the test for HIV has been done. After being tested, the client is counselled again to prepare him/her to receive and cope with the test results. In this counselling session the Counsellor will also work with the client to develop a risk-reduction plan for those who test negative and steps that the client can take to live positively for those who test positive (National Guidelines for Voluntary Counselling and Testing, 2005).

7.4 Confidentiality of test results

7.4.1 As per Section 16, the results of an HIV test shall be confidential and shall be released only to the person tested. However, there is an exception to this generality whereby results may be released to a third party under the following conditions:

- a) in case of a child, his parent or recognized guardian;
- b) in case of person with inability to comprehend the results; his spouse or his recognized guardian;
- c) a spouse or a sexual partner of an HIV tested person; or
- d) the court, if applicable.

7.5 Duties of disclosure to partner/employer/insurer

Partner

7.5.1 Section 16(2)(c) provides that HIV test results may be released to a partner. Section 21(1) of the Act provides that any person who has knowledge of being infected with HIV after being tested shall-

- a) immediately inform his spouse or sexual partner of the fact; and
- b) take all reasonable measures and precautions to prevent the transmission of HIV to others.

Employer

7.5.2 The Occupational Health and Safety Act of Tanzania requires every employer to do a medical check-up before confirming someone as an employee. The rationale is to determine whether or not the person is capable of working in a certain environment. This means that the Employer's doctor will indirectly know the HIV status of the employee however he is bound by the duty of confidentiality as provided for by the Act.

Insurer

7.5.3 Section 24(l) of the Act might be relevant. A person being the owner, manager or in charge of health care facility or medical insurance provider, whether public or private, shall facilitate access to health care services to persons living with HIV and AIDS without discrimination on the basis of their status.

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

- 8.1 Section 47 of the HIV and AIDS (Prevention and Control) Act, 2008 states that “Any person who intentionally transmits HIV to another person commits an offence, and on conviction shall be liable to imprisonment for a term of not less than five years and not exceeding ten years”.
- 8.2 There are several successful cases regarding the criminalisation of willful transmission of HIV AIDS in Tanzania that are “unreported”. An example is at this link: <http://jabashadrack.blogspot.com/2012/11/mwanza-two-get-life-in-prison-for.html>. The case was based on two counts (a) defilement under SOSPA and (b) transmission of HIV AIDS to a minor.

9. FURTHER INFORMATION

- 9.1 Section 51 provides a mechanism of lodging a complaint against the contravention of this Act. That any complaint against contravention of any provision of this Act may be lodged in writing to -
 - a) The Secretary to the village, ward, district or urban AIDS Committees as the case may be;
 - b) The police station;
 - c) The owner, manager or the person in-charge of a health care facility concerned; or
 - d) The employer.
- 9.2 That every complainant shall be required to give all the necessary information in relation to the complaint in question.
- 9.3 And that the Minister may make regulations prescribing the mode of lodging and handling of complaints under this Act. To our knowledge the regulations are not in place.

10. REFERENCES

- 10.1 The “Act” means “HIV and AIDS (Prevention and Control) Act, 2008”
- 10.2 <http://www.moh.go.tz/>
- 10.3 National HIV Aids Program
- 10.4 Tanzania Food, Drugs and Cosmetics, Act No 1 of 2003
- 10.5 Guidelines for HIV Testing and Counselling in Clinical Settings, Ministry of Health Tanzania, July 2007
- 10.6 National Guidelines for the Management of HIV and AIDS

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