



Southern African AIDS Trust

**REPORT**

**REGIONAL**

**2014**



**REVIEW – BOTSWANA**

**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 2011<sup>1</sup> 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 2012<sup>1</sup>.** 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 distribution?” and “What are the human rights issues surrounding HIVST?” The review looked across

<sup>1</sup> UNAIDS 2013; WHO 2013

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 Botswana. This report is intended to inform SAT and all its strategic partners about the legal framework and human rights implications relevant to HIVST in Botswana.

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 Botswana and across the region.

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

Jonathan Gunthorp



Executive Director - SAT

## ACKNOWLEDGEMENTS

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Special thanks go to Rantao Kewagamang Attorneys (Botswana) who provided pro bono legal services to undertake the review on HIV Self-Testing in Botswana 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.

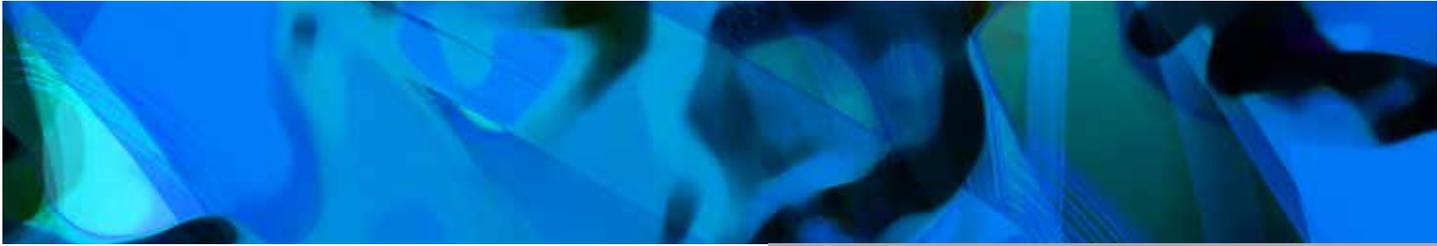
SAT is grateful to Wits Reproductive Health Institute for all their technical support and input during the March 2014 HIV Self-Testing Consultative Workshop.

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.

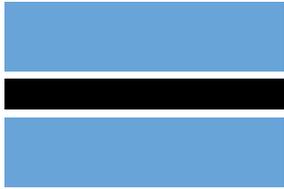
## **DISCLAIMER**

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REVIEW



# BOTSWANA

**BOTSWANA**

**RANTAOKEWAGAMANG ATTORNEYS**

**(KELEBOGILE KEWAGAMANG)**



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## 1. INTRODUCTION/BACKGROUND

- 1.1 Issues concerning HIV are dealt with under the Public Health Act (the “PHA”). It is a fairly new piece of legislation which was assented to on the 4th September 2013. HIV testing, prevention and control are dealt with under Part XII of the Act, from Sections 104 to 122. It is also dealt with under general provisions relating to communicable diseases. This research shall focus on this Act as it is the only piece of legislation that regulates matters the subject of this research. Where-ever reference is made to an ‘Act’, such reference shall be to the Public Health Act.
- 1.2 Reference to the ‘Minister’, in this research, is reference to the Minister of Health, and reference to the ‘Director’, is reference to the Director of Health Services

## 2. SUMMARY OF ADVICE

- 2.1 HIV Self- Testing falls within the purview of the Public Health Act. (Hereinafter referred to as ‘the Act’ or P.H.A) This Act explicitly prohibits self-testing. As a result, the research, which is mainly on self-testing, is not extensive and will have limited utility for SAT unless the law is changed on this aspect. Self-testing is also an issue that has never been specifically interrogated in this jurisdiction (ie self-testing and self-testing kits, self-testing and ancillaries whether it be kits, mode of counselling etc). It was not part of the issues that formed the public debate of the Bill leading up to the Enactment of the Public Health Act. There is still a lot of space for discourse on the matter in Botswana. However, at the moment, due to the novelty of the legislation, and the fact that for the ordinary member of the public, it is a complicated Act dealing with a broad number of public health issues, digestion of this law would take some time. The fact that regulations have also not been promulgated makes the Act incomplete and unenforceable in part. The issue of self-testing has so far not been topical, it was not one of the topical issues in the debates leading up to the enactment of the Act.

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

- 3.1 HIV Self-Testing is not legal in Botswana. Section 119 of the Act provides that a person shall not carry out an HIV test unless the test is carried out in a centre, structure or health facility approved for the purpose of carrying out HIV testing. The Act does not even define Self-testing or have a definition for an HIV Self-testing kit. Section 120 provides further, that a person shall not manufacture or sell, to another person, a device for the purpose of carrying out an HIV test, except where the other person is a representative approved for that purpose by an institution recognised in the Act. For self-testing kits to be sold, these sections would have to change and specifically allow for self-testing, together with the necessary procedures and safe-guards that would go with it. This is an issue, which in our view, would generate a lot of public debate, taking cue from the debate on compulsory testing. Botswana, as a matter of policy, prioritised issues of HIV, and they normally generate a lot of debate when put out to the public, especially through civic society organisations. The turn- around time for changing the law would depend on the sponsor for such change and the political will to push through the legislation. The amendment has to go through parliament just like any other law.
- 3.2 There are testing centres in Botswana, like Diagnofirm and Tebelopele. In terms of the Act, these would be centres approved for testing by the Minister. Presently, it is not clear from the Act under which conditions these centres would be approved, because of the absence of regulations. Field visits to these centres might provide an answer to this question. HIV testing is also done in public and private hospitals, private hospitals mostly send the specimen to Diagnofirm for analysis as they do not have labs equipped for the testing.

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

- 4.1 There is no law that governs HIV Self-Testing kits as self-testing is not allowed at all in terms of the law.
- 4.2 There is no law in Botswana that regulates even the HIV testing kits used in approved facilities. The country is in the process of coming up with such laws, and is currently doing a bench-marking exercise. The only law in place is the Drugs and Related Substances Act. HIV testing kits do not fall within the ambit of this Act. The Ministry of Health, through the Department of Clinical Services (Medical Engineers), together with Botswana Unified Revenue Services, works with relevant professionals from the Botswana Health Profession Council to validate medical devices and ensure that they are operated by people with relevant qualifications. The Botswana Bureau of Standards has yet to develop a standard for HIV testing kits. There does not appear to be firm protocol on the validation of medical testing kits. Things would only become clear once the envisaged law is enacted.
- 4.3 It is not easy to say that the law that would apply to HIV testing kits would apply to ST kits as there is currently no law that applies to HIV testing kits. However, in our view, this would depend on a number of factors such as the nature of such kits and the level of skill needed to operate them. The principles of care and diligence necessary to safeguard the validity and accuracy of results should however be subject to the same legal principles.

## 5. WHAT ARE THE HUMAN RIGHTS ISSUES SURROUNDING HIVST?

- 5.1 There are no human rights issues specific to HIVST in Botswana as self-testing is not allowed. However, there are human rights issues concerning HIV in general. There are provisions in the Act that may violate the right to privacy, may offend the non-discrimination clauses in the Constitution of Botswana, and lead to cruel and degrading treatment. Since the question is specific to HIVST, it makes such issues not of the moment.

### 5.2 Does every person have a right to be tested?

- 5.2.1 Yes. Section 104 (1) of the Act states that the Minister of Health shall ensure that confidential HIV testing facilities are made available to a person of the age of 16 and above, who requests an HIV tests in respect of himself or herself.

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

- 5.3.1 The Act, in Section 116, makes it mandatory for persons infected with HIV to disclose their status to their sexual contacts and care givers. If they do not, after a reasonable opportunity so to do, a medical practitioner is mandated to do so on their behalf.

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

- 5.4.1 Yes, a person can be forced to take a test. In terms of Section 104 (2) (3a) routine HIV testing may be offered to any person in accordance with procedures or guidelines issued by the Director for the purpose of facilitating access to health related programmes and services. Subsection (b) empowers the Director or his delegate, where necessary and reasonable, to require a person or category of persons to undergo an HIV test. If a person refuses to undergo a test in terms of subsection (3), the Director may apply for an order before a Magistrate, to compel that person to undergo a test. A director is defined in the ACT as the Director of Health Services, who, in terms of Section 15, shall be a medical practitioner, and have specialised qualifications in the area of clinical or public health. The Minister of health has oversight over the Director.

- 5.4.2 In determining whether to grant that order, the magistrate has to consider;

- a) Whether another person is or has been exposed to the possibility of transmission of HIV
- b) The right to information of the person exposed to the possibility of transmission of HIV
- c) Availability of treatment in relation to HIV

The order has to be made only if they are convinced that it is in the interest of public health or in the public interest to make the order.

- 5.4.3 Section 105(2) empowers medical practitioners responsible for the treatment of a person, to conduct an HIV test without the consent of that person, where the person is unconscious and unable to give consent, or, in their view, the test is clinically necessary or desirable in the interests of that person. Section 105(3) gives the medical practitioner criminal and civil immunity in such cases.

- 5.4.4 A person who offers to donate any tissue or whose tissue is offered to be donated is required to undergo an HIV test immediately before the donation is carried out, in terms of Section 106.

- 5.4.5 In terms of Section 109 (3) , a medical practitioner may require a person who does not need urgent surgical or dental procedure, to undergo an HIV test before carrying out that procedure.

5.4.6 Further, in terms of Section 108, a person convicted with the offence of rape or defilement under the Penal Code shall be required to undergo an HIV test. If the test is positive, the person would then receive a stiffer sentence in terms of Section 142 (4) of the Penal Code (CAP 08:01) The sentence would be stiffer where it is proven that the person convicted was aware that they are HIV positive.

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

5.5.1 Discrimination on the basis of one's HIV status is not allowed as it will offend against the right to equality and freedom from discrimination guaranteed in Sections 3 and 15 of the Constitution of Botswana. Exceptions to this rule are: where it is in the public interest, respect for the rights of others, instances where the law is discriminatory with respect to persons who are not citizens of Botswana, or where the discrimination is justifiable in a democratic society. There is no law that prohibits a doctor with HIV from performing surgery, unless their performance of that surgery can be classified under the above exceptions. In fact, under Section 104 (2), a person shall not induce another to undergo an HIV test for the purpose of any employment.

## **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 HIV Self-Testing is not legal in Botswana. However, in approved health facilities, the law, ie common law, requires those who carry out testing to ensure that it is done with care, and will be liable where there was negligence. This would apply even to SAT were it to sell faulty kits, or give them out for free, under the law of delict, where it can be established that SAT owed the person a duty of care, or under the law of contract, depending on the facts at hand.
- 6.2 Third parties could also sue the supplier so long as they can establish a nexus for their loss/ damage and the supplier's negligence.
- 6.3 The heads of claim under which damages are assessed comprise pain and suffering and emotional distress resulting in some physical manifestation. There are also special damages like loss of earnings and future earnings and loss of earning capacity.
- 6.4 The quantum of damages is very conservative in this jurisdiction. Seldom are punitive damages awarded. There is also a requirement for the claimant to mitigate their loss.

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

- 7.1 It is worthy to note that although pre-test counselling is explicitly provided for, no specific provision has been made for post- test counselling. There is a duty placed on the Director to ensure that adequate counselling is done for people infected with HIV, however, no details are given as to when, where, how and by whom such counselling should be done.
- 7.2 HIV is also considered a notifiable disease under the terms of the Act. Under Section 111 and 112, where a person tests positively for HIV, a medical practitioner carrying out the test is required to record the result in a form approved by the Minister and submit it to the Ministry of Health 'as soon as possible' (no time limit is set), subject to confidentiality guidelines.

### **7.3 Must a person consent to testing (is written consent required)?**

7.3.1 Section 105 of the Act states that an HIV test shall not be conducted in respect of another person except with their consent, or, if under 16 years of age, with the consent, in the prescribed form, of the parent of that child or guardian in the case of persons with disability. The legal consequences are not spelt out in the Act, however, a claim for damages would lie for violation of the right to privacy under delict. This is subject to the exceptions on compulsory testing described in section 4.4. The form of consent is not yet clear.

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

7.4.1 The legal age for consent is 16 years. Where the person is less than 16 years of age, parental consent is required, and this is in terms of Section 105 (1) (b). A person with a disability, who is over 16 years of age, which renders them incapable of giving consent, can be tested with the consent of their parent or guardian and other persons in the order provided in Subsection (c).

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

7.5.1 The Act makes provision for pre-test counselling in Section 110. Before an HIV test is undertaken, a medical practitioner is mandated to provide information to the person who wants to test and any other person the medical practitioner considers should be informed, of the medical and social consequences of being tested. The P.H.A does not set out what this information would be, so any answer I give would be purely speculative. This is one aspect that would hopefully, be made clear in the regulations.

7.5.2 Section 116(3) places a duty on the Director to ensure that a person infected with HIV has received adequate counselling, medical and psychological assessment as well as treatment. The Act however, does not indicate at what stage the counselling will be carried out post testing.

#### 7.6 Confidentiality of test results

7.6.1 The right to confidentiality is emphasised in a number of sections in the Act. In terms of Section 104(1) (a), a person over the age of 16 is entitled to confidentiality of the test results. For this purpose, the Minister of Health is required to ensure that confidential HIV testing facilities are made available.

7.6.2 Further, the Minister is required, in Section 113, to issue guidelines for the confidentiality of HIV test results. Sections 113 (3) states that a person shall not deal with the test results contrary to the guidelines.

7.6.3 In terms of Section 114, the recording of HIV test results must not directly or indirectly reveal the identity of the person tested, except in line with the guide lines

7.6.4 Although the Minister is enjoined to make these guidelines, at present, the Act is in force but the guidelines have yet to be made. The Minister can be compelled to release the guidelines, so long as the Applicant satisfies the requirements for locus standi. The law in Botswana does not cater for class action/ public interest lawsuits, so you would have to demonstrate sufficient interest/ connection, in the matter

#### 7.7 Duties of disclosure to partner/employer/insurer

7.7.1 Section 115 of the Act makes consent a pre-requisite for disclosure of information concerning the result of an HIV test.

7.7.2 With regard to partners, Section 116 (2) of the Act, a person who is aware of being infected with HIV, shall inform, in advance, any sexual contact or care giver or a person with whom sharp instruments are shared, of the fact of being HIV positive. If they are constrained so to do, they may, in terms of Section 116 (4), in writing, request a medical practitioner or approved health care worker to inform and counsel a sexual contact or care giver.

7.7.3 A medical practitioner responsible for treating a person infected with HIV, may, after consultation with an approved specialist, inform any sexual contact or care giver of that person of the person's status, if the person failed to do so after a reasonable opportunity. This is in terms of Section 116 (7) of the Act.

7.7.4 There is no requirement for disclosure to the employer or insurers. Under Section 104 (2), a person shall not induce another to undergo an HIV test for the purpose of any employment.

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

8.1 Section 116(9) allows the Director of health services to apply to a Magistrate for an order, where the Director believes that a person with HIV 'knowingly or recklessly places another person at risk of becoming infected with HIV without the knowledge of that person of the infected person's status. In terms of Section 116(10), the magistrate has the power to order the person with HIV to undergo medical and psychological assessment; to impose restrictions on the behaviour or movement of that person for a period of up to 28 days, (which can be renewed), or to isolate and detain that person for up to 28 days. 28 days is the maximum number of days a person shall be detained at a time. This is the most severe sentence that can be handed down

8.2 When making the order 116 (9), the Magistrate must take into account

- a) Whether, and by what method, the person transmitted HIV;
- b) The seriousness of the risk of the person infecting other persons;
- c) The past behaviour and likely future behaviour of the person;
- d) Any other matter the magistrate considers relevant.

8.3 The proceedings hereunder are held in camera.

8.4 The Act however, does not set out the application process in detail, whether it will be exparte, legal counsel allowed, for instance.

8.5 In addition to the above provisions, The Penal Code, CAP 08:01, provides, in Section 184, that a person would be guilty of an offence if they unlawfully or negligently do any act which is, and which they know or have reason to believe, likely to spread the infection of any disease dangerous to life. The punishment is provided for in Section 33, which is imprisonment for a term not exceeding 2 years with or without a fine. This section is not specific to HIV/ AIDS but has been used to prosecute people for wilful transmission. There is one known but unreported case, State v Morwamang, however, the prosecution was unsuccessful for lack of evidence to prove intention to wilfully transmit HIV/ AIDS.

## 9. FURTHER INFORMATION

- 9.1 At present, the Act does not have Regulations, and the Minister has not yet provided guidelines mentioned in the Act. Once these are made, the answers to some of the questions may differ.
- 9.2 There is however, an April 2012 HIV/ AIDS policy that was drafted before the Act. The policy does not deal with HIV/ AIDS testing and is in essence not different from the Act on this issue. Part 2 of the policy deals with Screening and Testing for HIV Infection. The preface reads as follows;  
*'The critical importance of HIV screening for all age groups cannot be over- emphasized. HIV testing should continue to be universal, routine, and on an 'opt out' basis. HIV testing should be conducted in all clinical and outreach settings throughout the country by all healthcare providers'*
- 9.3 The policy is generally more detailed than the Act. It recommends different testing method for different age classifications; less than 18 months,18 months and older, adolescents, and pregnant women. Self- Testing is however, not recommended for any category.
- 9.4 The policy encourages HIV testing but states clearly that 'at no time should the patient be pressured or coerced to undergo HIV testing. This of course, has been changed in the Act, which introduced coercive testing.
- 9.5 The policy provides for both pre and post test counselling. Post-test counselling is tailored in accordance with the test results. However, regardless of the test, safe sex practices have to be reviewed, routine tuberculosis screening done, sexual and reproductive health and family planning discussed. These provisions may help bridge the gaps in the Act as counselling procedures are not detailed.
- 9.6 For Self-testing however, only advocacy for law reform may work as it is explicitly prohibited.

## 10. REFERENCES

- 10.1 Public Health Act, 2013
- 10.2 Drugs and Related Substances Act; CAP (63:04)
- 10.3 Underlying Principles and Rationale of the 2012 Botswana National HIV & AIDS Treatment Guidelines: 1 April 2012 Edition
- 10.4 The Penal Code, CAP 08:01



# SOUTHERN AFRICAN AIDS TRUST

**"COMMUNITY SYSTEMS FOR HIV AND  
SEXUAL & REPRODUCTIVE HEALTH &  
RIGHTS"**



Southern African AIDS Trust

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