



Southern African AIDS Trust

REPORT

REGIONAL

2014



REVIEW – ZAMBIA

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

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, www.satregional.org .

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 Zambia 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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ZAMBIA

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1. INTRODUCTION/BACKGROUND

- 1.1 The HIV/AIDS pandemic in Zambia has become relatively widespread. The effects of HIV/Aids have contributed to the developmental challenges that continue to plague Zambia. Consequently, the Zambian Government has through the development of a legislative and policy framework sought to develop a strategic approach for mitigating the impact of HIV/AIDS.
- 1.2 An important strategic tool, which the Government has sought to utilize, is the promotion of HIV testing as a means of preventing infections and as an entry point for HIV/AIDS treatment. Several guidelines have consequently been developed which seek to enhance the benefits of voluntary testing and counselling. There is however, still a need for the government to explore additional prevention and treatment strategies. It is in this regard that consideration of the issue of HIV self testing is pertinent in the Zambian Context

2. SUMMARY OF ADVICE

- 2.1 HIV Self Testing in Zambia is largely unregulated. In addition to the foregoing, there are no specific laws, policies or guidelines which address the manufacture, distribution, sale or use of HIV self testing kits. The kits do however come within the ambit of laws which regulate the utilization of medicines and medical devices and require the obtaining of licenses and permits before distribution of the same.
- 2.2 The above notwithstanding, the use of self testing kits in Zambia are not wide spread as the current policy on HIV testing is one of Voluntary Testing and Counselling. There is an emphasis by the National HIV/AIDS Policy framework on there being a link between counselling and HIV testing. This renders self testing undesirable in the context of the national HIV/AIDS strategic approach.
- 2.3 In terms of possible human rights issues surrounding HIV self testing, these are captured generally under the Constitution, various pieces of legislation, policies and guidelines. These protections relate to the recognition of the right of persons living with HIV/AIDS to privacy, to non-discrimination, to the highest attainable standard of physical and mental health and to the rights to informed consent before a medical procedure is carried out. Notably, in relation to people living with HIV/AIDS, the Zambian courts have asserted the right to privacy as well as prohibited mandatory testing
- 2.4 There is a statutory protection for patients, in terms of liability of any distributor of medical devices or kits, if such devices or kits are faulty or give inaccurate diagnosis. In addition to this, users of kits may also have recourse to contract or tort law to assert any claims. The statutory protection does not however extend to third parties who may suffer damage as a result of faulty kits.

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

- 3.1 The National HIV/AIDS/STI/TB Council Act No.10 of 2002 (the “NAC Act”), which is the principal piece of legislation enacted to address the issue of HIV/AIDS, does not specifically make it legal or illegal to conduct HIV self-testing. The NAC Act deals primarily with the establishment of the National HIV and AIDS/STI/TB Council (The National AIDS Council (NAC)) which coordinates the national HIV/AIDS response. The NAC Act also constitutes the Secretariat of the NAC. One of the responsibilities of the Secretariat is to develop guidelines for testing in respect of HIV, AIDS, STI and TB. Please note that these are guidelines and not law.
- 3.2 Accordingly, there is no law in Zambia that expressly addresses the issue of HIV Self-Testing and no legislative conditions provided for the utilization or distribution of HIV self testing kits. To the extent that there is no law which expressly prohibits the use of self testing kits, it may be argued that their use is legal.
- 3.3 Based on the application of the common law principle that “a person should not be penalized under a law that is not clear” it is unlikely that any penalty would accrue to person who conducts HIV Self testing.
- 3.4 However, an important consideration would be that based on the national policy on HIV testing, HIV self testing, while in the strict sense being deemed legal, would still not be desirable. In addition, it is possible that importation and distribution of self testing kits may be challenged if the Zambia Medicines Regulatory Authority considers that it is not in the public interest that such devices should be made available to the public. Please refer to our response in 4.5.

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

- 4.1 The absence of a legislative framework dealing specifically with HIV Testing also entails that HIV self-testing is not regulated. This also entails that the term HIV self-testing is not defined and that there is no technical definition for the HIV self testing kit
- 4.2 However, an analysis of the various policy documents and national guidelines which inform the national response for the prevention and combating of the spread of HIV/AIDS, reveals that, although not prohibited, HIV Self-Testing is not encouraged as a method of HIV Testing. The national HIV testing approach, which is set out in the National HIV/AIDS/STI/TB Policy of 2005 (the “Policy”), is standardized and comprehensive Voluntary Counselling and Testing (“VCT”). The requisite link between counselling and HIV testing renders self testing undesirable.
- 4.3 Additionally, the National Guidelines on HIV Counselling and Testing (the “VCT Guidelines”) which have been developed pursuant to the NAC Act emphasize that “Testing demands a very high degree of accuracy, thus only those who have been properly trained in the art of HIV testing may be involved in testing. Individuals carrying out such tests must be conversant with the test format, its correct usage and application. The person is expected to understand the principle of the test, its interpretation and the objectives of the quality control measure involved”.
- 4.4 The VCT Guidelines were developed by a multidisciplinary team representing public health workers, Non-Governmental Organizations, physicians, social workers, counsellors and laboratory experts under the auspices of the Ministry of Health. These guidelines arose from recognition for the need for comprehensive and standardized HIV counselling and testing operations throughout Zambia and were therefore formulated after widespread consultations with support groups, people living with HIV/AIDS (PLWHA), donors, the private sector, people with disabilities and many others experts.
- 4.5 The VCT guidelines are intended to serve as a ‘blueprint’ for the scaling up of HIV counselling and testing services and to help health workers and counsellors establish and maintain high quality HIV counselling and testing services in Zambia. Accordingly, the VCT guidelines apply to all health care providers and facilities whether public, private, military or mission based.
- 4.6 These guidelines do not have any force of law. Therefore, it does not appear that there are any prescribed legal consequences for failure to adhere to these guidelines. Health facilities do however voluntarily abide by the requirements of the guidelines as they are based on the best international practice. This being the case, failure to adhere to these standards may raise reputational issues more so with respect to private facilities which are operated primarily as businesses. Additionally, failure to adhere to these guidelines may potentially expose a health care provider to legal action for violation of constitutionally entrenched rights which are also recognised by the guidelines.
- 4.7 Based on the foregoing, it is likely that the Government may be opposed to the use of self-testing kits by untrained individuals.
- 4.8 Bearing in mind however, that the policy pronouncements and guidelines set out above are devoid of legal force, the Government could be engaged with a view to ascertaining the parameters within which it would permit the wide spread utilization and distribution of HIV Self Testing kits.
- 4.9 The above notwithstanding, the manufacture, distribution and sale of HIV self testing kits is however captured under the Medicine and Allied Substances Act No.3 of 2013 (the “MAS Act”). The MAS Act stipulates that a person shall not manufacture, distribute or deal in any medicine or allied substance without a pharmaceutical license. An allied substances includes a medical device, which is defined as including any instrument, apparatus, component, part or accessory manufactured or sold for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or the symptoms of the disease, or abnormal physical state in human beings or animals. HIV self testing kits fall under this definition. Any person who operates without a license commits an offence.
- 4.10 Additionally, the MAS Act regulates medicines and allied substances with respect to export and import permits, market authorization (subject to stipulated exceptions with respect to, inter alia, any allied substance used for purposes of a clinical trial) and advertising.
- 4.11 The MAS Act also prohibits the sale of any medical device that may cause injury to the health of the user when the medical device is used according to the direction on the label of, or accompanying, that medical device or for such purposes and by such methods of use as are customary or usual. In addition, the MAS Act prohibits the manufacture, import, sell or supply of any medical device that does not meet the prescribed standards of quality. Contravention of these provisions is an offence.

- 4.12 In addition to the above, the Zambia Medicines Regulatory Authority (the “Authority”) may where it determines that it is not in the public interest that any allied substance should be made available to the public, by notice, in writing, served on any person or in the Gazette, direct that person to return the allied substance which the person has in their possession to: the manufacturer of the allied substance, in the case of any imported allied substance; to the importer concerned, or deliver it or send it to the Authority or such other person as the Authority may designate.
- 4.13 As indicated above, the distribution of HIVST kits would be regulated under the MAS. A distributor of the kits would have to obtain a Pharmaceutical License from the Authority in order to manufacture, distribute or otherwise deal in HIVST kits.
- 4.14 Additionally, subject to specified exceptions, the HIVST kits cannot be placed on the Zambian market advertised, marketed, supplied, administered or dealt with in any other manner without marketing authorization from the Authority. Further, an import or export license would be required to import or export HIVST kits.

5. WHAT ARE THE HUMAN RIGHTS ISSUES SURROUNDING HIVST?

- 5.1 Human rights, in the context of HIV/AIDS, are generally captured by the protection provided by the Constitution Chapter 1 of the Laws of Zambia (the “Constitution”). The constitutional protection of persons living with HIV was confirmed by the High Court in Stanley Kangaibe and Another v The Attorney-General (2009) (unreported), in which it was ruled that mandatory testing for HIV is unconstitutional as it violates an individual’s right to privacy and to protection from inhuman and degrading treatment. In addition there are certain general laws, as highlighted below, which contain no specific reference to HIV/AIDS but may be used to protect the rights of persons living with HIV/AIDS.
- 5.2 Further, the Policy has the protection of human rights and prevention of stigma and discrimination as one of its cross cutting policy objectives.
- 5.3 More specifically, the VCT Guidelines require that, every person undergoing VCT is made aware that they have the following rights:
- The right to privacy;
 - The right to non-discrimination, equal protection and equality before the law;
 - The right to have a family;
 - The right to the highest attainable standard of physical and mental health; and
 - The right to informed consent before a medical procedure is carried out.
- 5.4 VCT providers are required to ensure that these rights of an individual are protected and that their counsellors recognize the fundamental rights, dignity and worth of all clients.
- 5.5 Does every person have a right to be tested (right to health)?**
- 5.5.1 The VCT Guidelines recognize the right to the highest attainable standard of physical and mental health in relation to HIV/AIDS by stipulating that “quality counselling and testing contributes to the physical and mental health of those who wish to know their HIV status and is an integral part for supportive medical care”.
- 5.5.2 Though this right is not expressly enshrined in any law, there is a deliberate policy towards encouraging every person to be tested. This is because there is a recognition that HIV Testing serves as an important entry point to HIV/AIDS Care, Treatment and Support services. The VCT guidelines promote voluntary as well as routine counselling and testing for HIV at all health facilities and community outreach settings. The Policy stipulates that the VCT service should be free of cost for users and encourages provider-initiated counselling and testing.
- 5.5.3 Further, in the context of a person’s right to health, the VCT Guidelines also emphasize the right to informed consent before a medical procedure. The guidelines recognize that it is a standard of medical practice that there should be informed consent before any medical procedure. Therefore, before HIV testing is conducted, the risks and benefits of the procedure should be explained to facilitate the process of informed consent.
- 5.5.4 There are however, with respect to minors, some restrictions on the right to be tested.
- 5.6 Can a person be compelled to make any disclosures concerning a positive diagnosis and, if so, in what circumstances? (Right to privacy)**
- 5.6.1 In the context of HIV, the right to privacy of a person enjoys constitutional protection. As indicated above, the High Court has held that mandatory testing for HIV without informed consent is unconstitutional as it infringes fundamental rights, particularly the right to privacy.

- 5.6.2 In addition, the right to privacy is addressed by both the VCT Guidelines and the Zambia National Guidelines for HIV Counselling and Testing of Children (the “**Children’s guidelines**”). The VCT Guidelines stress that a person’s interest in their privacy is particularly compelling in the context of HIV/AIDS, because of the stigma and discrimination attached to the loss of privacy and confidentiality if HIV positive status is disclosed.
- 5.6.3 In this regard, the National Guidelines require that HIV testing services set adequate safeguards to ensure that:
- testing occurs with informed consent;
 - confidentiality is protected, particularly in health and social welfare settings; and
 - Information on HIV status is not disclosed to third parties without the consent of the individual.
- 5.6.4 Privacy is protected through observing confidentiality in carrying out HIV testing, disclosing results and keeping records.
- 5.6.5 Based on the foregoing and subject to the exceptions highlighted in section 7.4 below, no person can be compelled to make any disclosures concerning a positive diagnosis without their informed consent.

5.7 Can a person be forced to take a test or compelled to have a child tested (right to health vs right to privacy)?

- 5.7.1 As indicated above, mandatory testing is generally prohibited in Zambia. However because there is no specific legislation which addresses this issue, the prohibition of mandatory testing is not strictly enforced.
- 5.7.2 It is noteworthy that, in the context of labour matters, Section 28 of the Employment Act requires that every employee shall be medically examined by a qualified and competent Medical Officer before the employee enters into a contract of service of at least six months’ duration. The purpose of the examination is to ascertain the fitness of the employee to undertake the work which that employee is required to do. This provision does not however permit the testing of prospective employees for HIV/AIDS.
- 5.7.3 Moreover, the policy of the Zambia Federation of Employers is that employers should not require prospective job applicants to undergo an HIV test. According to this policy, the only relevant criteria of recruitment is whether or not the applicant has the requisite qualifications and is medically fit to do the job.
- 5.7.4 With respect to mandatory testing for children, the Children’s Guidelines are instructive. These guidelines stipulate that mandatory testing should only be done in the best interest of the child and without any form of coercion from the counsellor. The Children’s Guidelines highlight that, in line with the Constitutional right to life, in certain instances mandatory testing should be considered as a means of saving the life of a child. The guidelines further identify categories of children for whom testing is critical namely sick children, orphans and vulnerable children and sexually abused children. Although, if it is in the best interest of the child, that testing be compulsorily undertaken, it is critical that the informed consent from parents or guardians is solicited.

5.8 What is the law regarding discrimination based on a person’s diagnosis with HIV (discrimination/equality)?

- 5.8.1 In Zambia, generally all persons are protected from discriminatory practices. The Constitution of Zambia under Article 23 protects the right of an individual not to be discriminated against. Further, the Industrial and Labour Relations Act requires that all employees be treated equally without discrimination on the grounds of disability. Any worker who is discriminated against by an employer can file a complaint with Industrial Relations Court pursuant to sections 108 and 85 of the Industrial and Labour Relations Act. These laws, while being general laws with no specific reference to HIV and AIDS, may be utilized to protect the rights of people living with HIV.
- 5.8.2 The Citizens Economic Empowerment Act of 2006, however, specifically prohibits discrimination based on HIV status in companies defined as citizen empowered companies.

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 If a kit is supplied at no cost, the supplier would be generally liable for negligence under Tort.
- 6.2 However, where a person sells the kit rather than provide it free of charge, in addition to being liable for negligence under Tort or breach of warranty under the Sale of Goods Act, a supplier of HIV Self Testing Kits may also be liable under MAS (as indicated above) and the Foods and Drugs Act, Chapter 303 of the Laws of Zambia which protects the public against health hazards and fraud in the sale and use of food, drugs, cosmetics and medical devices.
- 6.3 Section 16 of the Foods and Drugs Act stipulates that: “Any person who sells any device that, when used according to directions on the label or contained in a separate document delivered with the device or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof shall be guilty of an offence”.
- 6.4 Section 31 (2) of the Food and Drug Act prescribes that a person found guilty of this offence shall be liable on conviction, in the case of a first offence, to a fine not exceeding one thousand penalty units (approximately US\$ 32.00) or to imprisonment for a term not exceeding three months, or to both and in the case of a subsequent offence, to a fine not exceeding two thousand penalty units (approximately US\$ 64.00) or to imprisonment for a term not exceeding six months, or to both.
- 6.5 The application of this Food and Drugs Act will, however, only apply where the supply of the goods is in pursuance of a sale or disposal for consideration.
- 6.6 Additionally, the Competition and Consumer Protection Act No. 24 of 2010 (the “CCP Act”) under section 49, provides that a person or an enterprise shall not supply a consumer with goods that are defective, not fit for the purpose for which they are normally used or for the purpose that the consumer indicated to the person or the enterprise. A person who contravenes this provision commits an offence and is liable, upon conviction to a fine not exceeding five hundred thousand penalty Units and in addition to pay the Competition and Consumer Protection Act Commission (the “Commission”) a fine not exceeding ten percent of that person’s or enterprise’s annual turnover.
- 6.7 In addition to the stipulated penalty, the Commission may also recall the product from the market or order the person or enterprise concerned, to pay a fine not exceeding ten percent of that person’s or enterprise’s annual turnover or three hundred thousand penalty units, whichever is higher, where the recalled product reappears on the market.
- 6.8 There does not appear to be any statutory basis upon which a supplier would be liable towards a third party in the circumstances set out. Nonetheless, it is possible that a third party may bring a claim under tort. The damage envisaged however, would most likely be deemed to be remote.
- 6.9 The summary of the potential liability identified in this Report is as follows:

Individual	Nature of Distribution	Type of Liability
Patient	Free	<ul style="list-style-type: none"> • Tortious liability (Negligence)
Patient	Sold	<ul style="list-style-type: none"> • Tortious liability (Negligence) • Breach of warranty under the Sale of Goods Act (where applicable) • Criminal Liability under the following laws: <ul style="list-style-type: none"> a) Medicines and Allied Substances Act b) Foods and Drugs Act c) Competition and Consumer Protection Act
Third party	Free	<ul style="list-style-type: none"> • Tortious liability (Negligence). Damage is however likely to be deemed remote.
Third party	Sold	<ul style="list-style-type: none"> • Tortious liability (Negligence). Damage is however likely to be deemed remote.

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 According to the VCT Guidelines the express consent of an individual is required before HIV Testing is conducted. The standard employed, in this regard, is that the consent should be informed consent. This entails that anyone conducting any HIV Testing should ensure that a person being tested understands all issues involved in counselling and testing before giving their consent for HIV testing. There is no requirement for written consent.
- 7.1.2 It is noteworthy that presentation with symptoms of disease to a health care facility implies a desire for diagnosis, therapy and care. This therefore, implies consent for diagnostic testing including for HIV. However, an “**opt-out**” approach should be used before testing. All patients must be informed that an HIV test is being done and have the right to decline or “opt-out” of the HIV testing. The opt-out approach is also employed with respect to routine testing for all patients being assessed in a sexually transmitted infection clinic, who are seen in the context of pregnancy to facilitate an offer of antiretroviral prevention of mother-to-child transmission or patients seen in clinical and community based health service settings where HIV is prevalent and antiretroviral treatment is available.
- 7.1.3 The VCT Guidelines additionally require that the rights of individuals whose ability to give valid consent to HIV testing may be diminished because of age, learning disabilities, or mental illness are carefully considered and also that the right of individuals to withdraw their consent at any time, even after their blood has been taken for HIV testing is respected.
- 7.1.4 The VCT Guidelines adopt the UNAIDS/WHO standard for mandatory screening for HIV and other blood borne viruses of all blood that is destined for transfusion or for manufacture of blood products. Accordingly, mandatory screening of donors is required prior to all procedures involving transfer of bodily fluids or body parts, such as artificial insemination, corneal grafts and organ transplant.
- 7.1.5 As indicated above, reputational risk and possible exposure to legal action by affected individuals are some of the consequences of failure to adhere to this requirement. A failure to obtain informed consent before HIV testing violates the constitutional right to privacy. This may entitle persons to seek judicial redress for the violation of fundamental rights under the Constitution particularly where the testing is conducted by government health care professionals and facilities.
- 7.1.6 Violation of the right to privacy may also present a risk of liability for medical negligence for private health care professionals and facilities particularly if the test results raises emotional and mental health issues for a person tested for HIV without consent.

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 HIV testing for children is guided by the VCT Guidelines and Children Guidelines. In line with the Penal Code Act No.15 of 2005, both these guidelines stipulate that any person who is 16 years of age and above should be considered able to give full and informed consent.
- 7.2.2 The consent of a parent/guardian is required if the child is below 16 years. However married, pregnant or parent-children are considered to be “emancipated minors” who should not be denied access to HIV testing services.
- 7.2.3 However, whether consent is given by the child or required to be given by the parent/guardian, the welfare of the child must be of primary concern when considering HIV testing for a child and accordingly testing may be deferred or refused if, in the assessment of the HIV Testing provider the testing is not in the best interest of the child.

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

- 7.3.1 The provision of counselling both before and after diagnosis is mandatory and is guided by the VCT Guidelines and Children Guidelines. The VCT Guidelines stipulate that counselling should be viewed as a means to initiate prevention and ensure access to continuing care and highlight that the objectives of counselling should be to:
- Ensure that people receive high-quality HIV prevention counselling to reduce their risk of transmitting or acquiring HIV, and have access to appropriate medical, preventive and psychosocial support services;
 - Promote early knowledge of HIV status through HIV testing and ensure that all people receive information regarding transmission, prevention, and the meaning of HIV test results; and
 - Ensure that people are helped to cope with the emotions and challenges they face when they are dealing with the possibility of being infected or are in fact infected.

- 7.3.2 The VCT Guidelines set out the rules/norms for counselling based on considerations of whether the counselling is given “pre-test” or “post-test” and whether it is follow-up counselling support. The following general rules apply in all instances; that the counselling should always be adapted to the needs of the client and that confidentiality should be maintained throughout the whole process of counselling.
- 7.3.3 The VCT Guidelines provide examples of issues to be addressed by the Counsellor during a pre-test counselling session. Some of the other issues addressed by the VCT Guidelines include, inter alia, the:
- a) Reasons why the client is requesting Counselling & Testing;
 - b) HIV testing procedures at the site, including whether or not written results will be given;
 - c) Basic facts about HIV infection and AIDS including modes of transmission and prevention;
 - d) Meaning of an HIV test, including the window period and possible results;
 - e) Personal risk assessment;
 - f) Client’s intentions after learning test results; and
 - g) Exploration of what the client might do if the test is positive, and the possible ways of coping with an HIV positive result including notification of significant others.
- 7.3.4 Post test counselling is required to consist of the following:
- i) Clients who test negative should be encouraged to return for additional testing within three months to make sure that they are truly uninfected.
 - ii) All clients whether HIV positive or HIV negative should be counseled about living positively;
 - iii) Every post-test counseling session should include the development of a risk-reduction plan specific to the client’s test results and personal life situation;
 - iv) The client is helped to deal with the issues of disclosure; and
 - v) Information on family planning, its role for both HIV positive and HIV negative clients, and how to have access to services should be included in counseling sessions.
- 7.3.5 The VCT Guidelines additionally provide guidance on special considerations when dealing with the following: premarital and marital services, discordant couples, counselling children and adolescents and prevention of mother to child transmission of HIV

7.4 Confidentiality of test results

- 7.4.1 The VCT Guidelines require all HIV test providers to maintain the highest standards of confidentiality (please refer to section 5.6 on the relevant right to privacy). HIV results must be kept confidential and shared with only those who need to know to provide appropriate care with the knowledge and consent of the client. Additionally, counsellors’ are required to take all reasonable steps to preserve the confidentiality of information obtained through client contact and to protect the identity of individuals, groups, or others, unless a client gives express permission to reveal it. The extent of this confidentiality should be clearly communicated to clients. Counsellors’ are also required to maintain confidentiality in storing and disposing of client records.
- 7.4.2 In general, HIV test results should be disclosed only to the client and in private. No information concerning the client, including HIV test results, should be given without the express content of the client.
- 7.4.3 However, the VCT Guidelines recognizes exceptions to the rule of confidentiality in the context of HIV/AIDS. These exceptions are universally acceptable and either do not breach the right to privacy or are required in the public interest and are provided by law, meeting the criteria for recognized restrictions under the Constitution. The exceptions listed in Appendix 2 include:
- Where the unequivocal consent of the client is given to share the information;
 - Where the information is to be given under compulsion of the law, for example as material evidence in court proceedings;
 - Where information is being shared among medical professional colleagues in a research or health-care setting;
 - Where cultural and social traditions permit shared confidentiality in the family and the community; and
 - In case of anonymous and unlinked testing.

7.4.4 The exceptions in Appendix 2 do not breach the right to privacy in the following regard:

- Where consent is given: no breach of privacy occurs as the client grants permission to do away with confidentiality.
- Compulsion of law: public interest considerations permit deviation from confidentiality requirement.
- Information shared among medical professionals: privacy is still protected by doctor-client confidentiality; therefore, no breach of privacy occurs.
- Shared confidentiality: this would only apply on the request of the person undergoing testing and with their full consent; there is no breach of privacy as permission to deviate from confidentiality requirement is granted.
- Unlinked testing: no breach of privacy occurs as the person's details linking them to their test results are not disclosed.

7.5 Duties of disclosure to partner/employer/insurer

7.5.1 There are generally no duties of disclosure imposed on a person living with HIV. A person is not obligated to inform their partner, employer or insurer of their status. However, the National Guidelines prescribe that all persons undergoing testing should be strongly encouraged to inform their sexual partners of their test results.

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

- 8.1 The transmission of HIV is not a standalone offence. It can only be inquired into, tried, and otherwise dealt with if the act comes within the scope of another offence under the Criminal Procedure Code, the Penal Code or any other written law.
- 8.2 This does not, however, entail that the transmission must have occurred during the course of a sexual offence. Where a person wilfully transmits HIV to another person in the course of having lawful sexual intercourse, the victim may have recourse to the penal code in establishing an offence by, for instance, lodging a complaint for indecent assault (which is an offence under the penal code). The perpetrator would then be charged with indecent assault and tried and sentenced in accordance with the penal code.
- 8.3 The offences to be relied on would depend on the ingenuity of the prosecution. We cannot therefore exhaustively list the possible offences that might be used to prosecute someone for transmission of HIV. However, the most likely in our view would include:
- i) Indecent assault
 - ii) Assault occasioning actual bodily harm
 - iii) Negligent act likely to spread infection
 - iv) Manslaughter (if death occurs)
- 8.4 Section 183 of the Penal Code creates the offence of “Negligent act likely to spread infection” which is committed when a person unlawfully or negligently does any act which is, and which s/he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life. A person who commits this offence is guilty of a misdemeanour. It is our opinion that this offence may be used to cover instances of reckless/negligent transmission of HIV.
- 8.5 The Policy expressly mandates the government to legislate against wilful transmission of HIV. In this regard, the Anti Gender Based Violence Act No.1 of 2011 when read together with the Penal Code criminalizes HIV transmission in the context of gender-based violence by including it within the definition of sexual abuse.
- 8.6 The Act defines sexual abuse to include “the engagement of another person in sexual contact, whether married or not, which includes sexual conduct that abuses, humiliates or degrades the other person or otherwise violates another person's sexual integrity, or sexual contact by a person aware of being infected with HIV or any other sexually transmitted infection with another person without that other person being given prior information of the infection”.
- 8.7 The test employed by the Anti Gender Based Violence Act is that of “a person being aware of being infected...”. In this regard, as long as a person is aware that s/he is infected and does not inform the victim of this fact, the Act does not concern itself with whether s/he intentionally transmits HIV or does so through some reckless or negligent behaviour. Accordingly, in our opinion this test would cover both wilful and reckless/negligent transmission.

- 8.8 The penalty for the offence of wilful and negligent/reckless transmission is determined depending on the offence for which a perpetrator is charged with and convicted of under the penal code or any other written law.
- 8.9 We are not aware of any cases instituted before the courts of law in Zambia related to the criminalisation of wilful transmission of HIV.

9. FURTHER INFORMATION

- 9.1 Consultations with the National Aids Council of Zambia and Ministry of Health officials have revealed that the Government of Zambia is giving some consideration to permitting the use HIV self testing kits in Zambia and in this regard has taken some steps towards evaluating specific testing kits. Additionally, some consideration has been given to carrying out nationwide consultations with a view to developing a policy and guidelines which would facilitate for the safe use of HIV self testing kits by ordinary citizens.

10. REFERENCES

10.1 Legislation:

- a) Constitution Chapter 1 of the Laws of Zambia¹
- b) National HIV/AIDS/STI/TB Council Act No.10 of 2002²
- c) Anti Gender Based Violence Act No.1 of 2011³
- d) Employment Act, Chapter 268 of the Laws of Zambia⁴
- e) Industrial and Labour Relations Act, Chapter 269 of the Laws of Zambia
- f) Foods and Drugs Act, Chapter 303 of the Laws of Zambia⁵
- g) Penal Code Act No.15 of 2005⁶
- h) Competition and Consumer Protection Act No. 24 of 2010⁷
- i) Citizens Economic Empowerment Act No. 9 of 2006⁸
- j) Medicine and Allied Substances Act No.3 of 2013⁹

10.2 Policies and Guidelines

- a) National HIV/AIDS/STI/TB Policy of 2005¹⁰
- b) National Guidelines on HIV Counseling and Testing¹¹
- c) Zambia National Guidelines for HIV Counseling and Testing of Children¹²

10.3 Case Law

Stanley Kangaibe and Another v The Attorney-General (2009) (unreported)

¹ <http://www.zamlii.org/zm/legislation/consolidated-act/1>

² http://www.ilo.org/wcmsp5/groups/public/---ed_protect/---protrav/---ilo_aids/documents/legaldocument/wcms_127558.pdf

³ http://www.zambialii.org/files/zm/legislation/act/2011/1/Anti-Gender_Based_Violence_Act%5B1%5D.pdf

⁴ <http://www.zambialii.org/zm/legislation/consolidated-act/268>

⁵ <http://www.zamlii.org/zm/legislation/consolidated-act/303>

⁶ <http://www.zamlii.org/zm/legislation/consolidated-act/87>

⁷ http://www.parliament.gov.zm/index.php?option=com_docman&task=doc_view&gid=714

⁸ <http://www.zambialii.org/files/zm/legislation/act/2006/9/cea2006284.pdf>

⁹ <http://www.zambialii.org/files/zm/legislation/act/2013/3/Medicines%20and%20Allied%20Substances%20Act%202013%20f.pdf>

¹⁰ <http://www.hsph.harvard.edu/population/aids/zambia.aids.05.pdf>

¹¹ http://www.k4health.org/sites/default/files/ct_guidelines_march_2006.pdf

¹² <http://www.k4health.org/sites/default/files/Zambia%20National%20Child%20Counselling%20%26%20Testing%20Guidelines.pdf>

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