



Southern African AIDS Trust

REPORT

REGIONAL

2014



REVIEW – SOUTH AFRICA

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

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 South Africa and across the region.

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

Jonathan Gunthorp



Executive Director - SAT

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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.

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REVIEW



SOUTH AFRICA

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NORTON ROSE FULBRIGHT SOUTH AFRICA

(INCORPORATED AS DENEYS REITZ INC)

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NORTON ROSE FULBRIGHT

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1. INTRODUCTION/BACKGROUND

- 1.1 Norton Rose Fulbright South Africa (incorporated as Deneys Reitz Inc) has been engaged to consider and comment upon the laws and practices governing HIVST in South Africa.
- 1.2 Although there is substantial learning on HIV and issues surrounding it, some of which are dealt with in this memorandum, HIVST and the distribution of ST kits are almost completely unregulated in South Africa.
- 1.3 The concept of HIVST is relatively new to South Africa and it is expected that undertaking the manufacturing and distribution of ST kits for use in South Africa may face opposition from various Government bodies. This is because of the exceptionalism attached to HIV as a unique disease requiring a specialised response, and the concern that a person who obtains a positive result from a self-test would not receive counselling, and therefore may suffer adverse consequences without any perceived support. Opposition may come primarily from the Department of Health, and the health professions. It is therefore recommended that, prior to undertaking distribution of ST kits in South Africa, relevant Government bodies, such as the:
 - Department of Health; and
 - South African Medical Association;
 are engaged with a view to debating issues surrounding HIVST and coming to an agreement or understanding as to the manner in which HIVST is to be performed and ST kits are to be distributed in South Africa.

2. SUMMARY

- 2.1 HIVST and the distribution of self-testing (**ST**) kits is presently not regulated in South Africa, except that pharmacies are prohibited from selling ST kits.
- 2.2 Generally, informed consent is required for a test and pre- and post- test counselling may be seen as elements of informed consent. The person undergoing the test may, however, refuse counselling. The circumstances under which a person may be compelled to be tested are legislated.
- 2.3 The Constitution plays an important role in matters of confidentiality of and discrimination based on HIV diagnosis. Confidentiality may only be breached in very limited and largely legislated circumstances. Discrimination based on HIV status breaches a number of statutes including the Constitution.
- 2.4 It is foreseeable that claims may arise following the use of ST kits, with liability being either contractual (although unlikely), delictual or statutory. It is suggested that manufacturers and distributors of ST kits take measures to educate consumers and reduce and/or exclude their liability. Criminal liability may also ensue in cases of intentional HIV transmission.

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

- 3.1 HIVST is presently not regulated in South Africa which means that there is nothing to stop kits from being distributed, except if kits are offered for sale through a registered pharmacy – where such sales are prohibited. There is presently no agreed or technical definition of HIVST in South Africa, it being a relatively new concept.
- 3.2 Registered pharmacists are prevented by the Good Pharmacy Practice (**GPP**) standards, 2010, issued by the South African Pharmacy Council from selling HIVST kits. The GPP make it clear that pharmacists must not sell HIVST devices for patients to perform tests “at home”
- 3.3 Technically, an HIVST is a “medical device” which may be regulated under the Medicines and Related Substances Control Act, 101 of 1965, or the Medicines and Related Substances Control Amendment Act, 72 of 2008. There is no mechanism for registering such ST devices under the 1965 Act, and the 2008 Act has not yet come into effect. There is no indication when the Act will come into force. It seems unlikely that present registration regimes would be able to deal with ST devices for practical reasons, since the authorities may not have the resources needed to licence the kits. That could place the issue of kits in jeopardy, and is another good reason to engage with the Department of Health early on in the process.
- 3.4 Section 68 of the National Health Act, 61 of 2003 deals with the withdrawal of a patient’s blood for testing, but does not contemplate ST.

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

- 4.1 No legislation presently governs the distribution of HIVST kits in South Africa. An HIVST is technically a “medical device” which the Minister has the power to regulate under the Medicines and Related Substances Control Act, 101 of 1965, or the Medicines and Related Substances Control Amendment Act, 72 of 2008.
- 4.2 Although an HIVST kit is a “medical device” as defined in the 1965 Act, the Act itself does not regulate medical devices. Section 35 of the Act authorises the Minister, through the proclamation of Regulations, to regulate aspects of particular medical devices. Sub-section 35(1)(xxvii) entitles the Minister to issue Regulations “*authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of any medical device or class of medical devices or medicines in respect of its safety, quality and efficacy*”. There are presently no Regulations issued in respect of HIVST kits.
- 4.3 The 2008 Act is not yet in force, and when it does come into force (at a date not yet known) there are practical issues which could hinder the registration of the kits or other similar kits.
- 4.4 The only regulation of HIVST kits of which we are aware is through the GPP standards issued by the South African Pharmacy Council. These standards prevent the sale of HIVST kits by pharmacists.
- 4.5 There are several policy documents and guidelines which deal with the counselling of patients who are tested for HIV. None contemplate self-testing.

5. WHAT ARE THE HUMAN RIGHTS ISSUES SURROUNDING HIVST?

5.1 Does every person have a right to be tested?

- 5.1.1. Section 27 of the Constitution of the Republic of South Africa, 1996, (Constitution) provides that everyone has the right to access to health care services and that no one may be refused emergency medical treatment. To date, this has not been interpreted to establish a right to free HIV testing, unless the test in question is compulsory. Occasionally, very minor exceptions are legislated. For example, in terms of section 131 of the Children’s Act, 38 of 2005, the state has to pay the costs of voluntary HIV tests done for the purposes of adoption or foster care.

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

- 5.2.1. The right to privacy is a fundamental human right in the terms of section 14 of the Constitution. A person’s HIV status is protected by the right to privacy and the disclosure of a person’s HIV status is a breach of the constitutional right to privacy.
- 5.2.2. Constitutional rights are not absolute and may be limited when they interfere with the rights of others (for example, the right to life of a partner). Theoretically, where the right to life outweighs the right to privacy, there could be a duty on a person to disclose their positive diagnosis to a person whose life they are endangering or on a medical practitioner to disclose one partner’s status to the other. Other than the compelled HIV tests discussed in 5.3 below, there are no known cases where such disclosure was compelled.

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

- 5.3.1. Generally, no one can be compelled to be tested. The legislation discussed below makes limited provision for compulsory testing in exceptional circumstances.
- 5.3.2. In terms of section 7(2) of the Employment Equity Act, 55 of 1998, an employer may make application to the Labour Court to allow the limitation of the right to privacy. The results of the test are confidential between the employer and employee.
- 5.3.3. Section 37 of the Criminal Procedures Act, 51 of 1977, provides that a police official may take such steps as deemed necessary to determine whether an accused has any “characteristic” or “distinguishing feature”, or shows any “condition”. Blood samples may be taken for such purposes and this section is worded wide enough to encompass tests for HIV. Again, the right to privacy would require that the accused’s HIV status be kept confidential.
- 5.3.4. In terms of sections 30 and 32 of the Criminal Law (Sexual Offences and Related Matters) Amendment Act, 32 of 2007, a victim of a sexual offence, an interested person on her behalf or the investigating officer, may make application for a compulsory HIV test of the accused. The results may be disclosed to a number of persons. See 7.4 for more detail.
- 5.3.5. In terms of section 130 of the Children’s Act, 38 of 2005, a child under the age of 12 years may only be tested with the consent of a parent or the responsible party (designated child protection organization or similar). A child over the age of 12 years may only be tested with his/her own consent. In either case, where the consent is unreasonably withheld, the Children’s Court may compel testing. See 7.2.4 for more detail.

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

- 5.4.1. The constitutional right to equality in terms of section 9 of the Constitution provides for protection against unfair discrimination. Various prohibited grounds for discrimination are listed, such as race, gender and disability. This is not a closed list. Accordingly, whilst HIV status is not specifically listed, it has subsequently been found to be similar to the listed grounds, which means that the Constitution prohibits unfair discrimination based on a person's HIV status.
- 5.4.2. In compliance with the constitutional imperative to combat discrimination, similar prohibitions against discrimination have subsequently been incorporated into other legislation: most prominently the Promotion of Equality and Prevention of Unfair Discrimination Act, 4 of 2000, dealing with protection against discrimination in general, and section 6 of the Employment Equity Act, prohibiting discrimination against employees and applicants for employment. HIV status is specifically included in both instances as a prohibited ground for discrimination.

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 Although it is not possible to predict all the circumstances in which claims might be brought against the manufacturers or distributors of HIV ST kits as a result of the test misdiagnosing a person's HIV status, **general classes of** potential claims immediately spring to mind.
- 6.2 Two possible general classes of claims are:
- In cases of a false positive result – claims for emotional trauma.
 - Claims for losses flowing from acts undertaken following the results of a self-test.
- 6.3 Under the second general category above, claims may vary from compensation for medical expenses incurred for tests carried out by specialists following a false positive result or claims by third parties who have been infected with HIV after a testing kit gave a false negative result. It is not beyond the realms of possibility to foresee claims brought by dependents of individuals who have committed suicide as a result of a false positive test result.
- 6.4 In each case a court will be called upon to determine whether the elements establishing a claim have been proved.
- 6.5 In South African law there are three basic types of liability.
- Contractual Liability
 - Delictual Liability
 - Statutory Liability

Each is discussed separately below. We also consider below potential ways of reducing the risk of liability.

6.6 Contractual liability

- 6.6.1. In order to establish a contractual claim for liability a user of the test kits will be required to prove (i) the existence of a contract, (ii) the material terms of that contract and (iii) that one of the terms of the contract was breached, resulting in harm to the user.
- 6.6.2. In the event that ST kits are sold, a contractual relationship will be created between the seller and the purchaser of a kit – such contracts of sale are commonplace and are established each time customers purchase goods at retail outlets.
- 6.6.3. It appears to us that, in order to found a claim for contractual liability a user would have to prove that it was a term of the contract of sale that the ST kit would be fit for the purpose for which it was bought ie that it would provide an accurate diagnosis of the users' HIV status.
- 6.6.4. Ordinarily, sellers in day-to-day sales transactions do not warrant the fitness for purpose of the products sold nor the quality of the goods sold. Usually such contracts are limited to an agreement to deliver a product upon payment of the purchase price.
- 6.6.5. The position may be different if such warranties are expressly given by the seller or if they can be implied from the circumstances surrounding the sale. It may be possible to imply such warranties if, for example, the seller holds itself out as being an expert in relation to the goods sold and/or makes representations in respect of the product beyond mere sales talk or if the seller is also the manufacturer of the product.
- 6.6.6. To establish a breach a purchaser/user would have to establish that such a warranty was given (ie. that the warranty was a term of the contract of sale) and that the warranty was breached by the seller.
- 6.767. If the product is sold generally, it appears unlikely to us that a party who has suffered loss as a result

of receiving a false positive or false negative result after using an HIV ST kit is likely to pursue a contractual claim. Though difficult to conceive of, it may be that claims are brought on this basis if there is a peculiar factual scenario which warrants such a claim. In those circumstances a claimant will have to prove the elements set out above in order to be successful.

6.6.8. The position in relation to contractual liability is unlikely to be different if the kit is provided free of charge rather than sold. The legal inquiry will involve similar elements having to be proved by the person who institutes the claim (ie they will have to prove a contract, the material terms of the contract, a breach of one or more of the terms and a resultant loss).

6.6.9. The main difference, if the kit is provided free of charge, is that the contract is likely to be characterised as one of donation rather than one of sale. The result is that certain implied terms, which are presumed by law to be part of a contract of sale, will not be applicable if the contract is one of donation. However, none of these terms are likely to affect a claim for loss caused by a false test result.

6.7 Delictual liability

6.7.1. In order to establish delictual liability a party must show that an offending party committed an act or omission which was wrongful and negligent and which caused loss or harm.

6.7.2. Act / omission

6.7.2.1 Whether there has been an act or omission in each instance will be a question of fact.

6.7.2.2 The act or omission requirement is likely to be the sale/provision of a ST kit which provides a false diagnosis of the user's HIV status.

6.7.3. Wrongfulness

6.7.3.1 In order for an act or omission to be wrongful it must be one which offends the *boni mores of a community or, put differently, one which the morals of society deem ought to be visited with liability. Essentially the question of whether an act or omission is wrongful is a discretionary policy decision exercised by the courts and guided by legal and constitutional principles.*

6.7.3.2 If the harm caused by an act is physical damage, the law presumes that the act was wrongful. As one moves into the realms of omissions, economic loss, consequential damages and so on, the question of wrongfulness becomes vexed.

6.7.3.3 Wrongfulness will be assessed by the courts on a case by case basis.

6.7.4. Negligence / Fault

6.7.4.1 In order to establish negligence or fault a claimant must establish that the act or omission in question is such that a reasonable person would have foreseen that it would cause harm and would have taken reasonable steps to prevent it.

6.7.4.2 In the section below dealing with possible methods of reducing the risk of liability we suggest ways in which the risk of a court finding that the seller/producer of a ST kit can be reduced.

6.7.5. Causation

6.7.5.1 In order to establish delictual liability a party must show a causal link between the act or omission complained of and the harm/loss suffered. The party seeking to establish the delict must prove that the act was both the factual cause and the legal cause of the harm/loss.

6.7.5.2 Factual causation is established using the *sine qua non test*. *This test involves establishing whether the loss/harm would have happened if the act or omission had not occurred. One imagines away the act complained of and then tries to evaluate whether the harm would have occurred in any event. If the harm would have occurred regardless of the act or omission complained of then the act or omission is not the factual cause of the harm or loss.*

6.7.5.3 Once factual causation is established, one must still prove that the act was the legal cause of the harm. This is also called the remoteness test. If a particular harm or loss is determined to be too remote a cause of the act or omission, the act is not the legal cause of the harm despite the fact that it may be a factual cause of the loss.

6.7.5.4 Whether a party alleging delictual liability will be able to establish causation will depend heavily on the particular facts of the claim and the harm alleged.

6.7.6. Loss/Harm

- 6.7.6.1 In order to establish a delict the claimant must prove that a wrongdoer's act caused harm. An act or omission which causes no harm cannot be used to establish a delict.
- 6.7.6.2 The absence or existence of harm is also a question dependent on the facts of each case.
- 6.7.7. Prior to the coming into force of the Consumer Protection Act, 68 of 2008 (the Act) (discussed below) one would have expected the majority of the anticipated claims to be brought as delictual claims. Such claims are still possible despite the existence of the Act although the Act provides a much easier route for the pursuit of such claims, particularly because it provides for strict liability (ie liability regardless of negligence or fault) where the provisions of the Act have not been complied with.
- 6.7.8. There is no difference in respect of potential delictual liability if the kit is provided free of charge as opposed to being sold. The elements of a delict must be proved and apply irrespective of whether the kit is sold or provided free of charge.

6.8 Statutory liability

6.8.1. Consumer Protection Act

- 6.8.1.1 The Act is a specific piece of legislation which regulates commercial interactions between suppliers, sellers and purchasers/consumers. The provisions of the Act supplement the common law delictual liability and provide enhanced protection for consumers.
 - 6.8.1.2 Part H of the Act sets out consumers' rights to fair value, good quality and safety. Section 55 of the Act guarantees a consumer's right to goods that are of good quality and that are reasonably useful, practicable and safe as a consumer is entitled to expect in the circumstances.
 - 6.8.1.3 If the consumer has informed the supplier that it requires goods for a particular purpose and the supplier either ordinarily supplies those goods and/or acts in a manner consistent with being knowledgeable about those goods, the consumer has the right to expect the goods to fulfil the particular purposes specified.
 - 6.8.1.4 However, the Act also provides that in determining whether goods satisfy the requirements of section 55 one must consider, amongst others, any instructions or warnings in respect of use of the goods.
 - 6.8.1.5 Section 61 of the Act provides that , the producer, importer, distributor and retailer of goods which are unsafe, defective, or contain inadequate warnings regarding hazards associated with the use of the product is liable for any harm which occurs as a result, regardless of whether there is any negligence or fault on the part of any of those parties. The section effectively provides for joint and several liability of all the parties involved in the production and distribution of a product, regardless of whether any of the parties acted negligently.
- 6.8.1. The Act applies to all 'transactions'. Transactions are defined as the supply of goods or services in the ordinary course of business for consideration. At first blush it would appear therefore that the provisions of the Act do not apply if the kits are provided free of charge as, in that circumstance, no consideration would be given. However, Part H of the Act provides for consumer's rights and the definition of 'consumer' in the Act includes *'...a user of...particular goods...irrespective of whether that user, recipient of beneficiary was a party to a transaction concerning the supply of those particular goods...'* It appears therefore that the provisions of Part H, discussed above, apply regardless of whether the kits are sold or provided free of charge.

6.9 Methods of addressing and reducing risk of liability

- 6.9.1. It is reasonably foreseeable that HIV ST kits may provide false-positive or false-negative results. It is also reasonably foreseeable that people who have taken the test may suffer harm which they would not have suffered had the kit provided the true result. Therefore, in order to reduce the risk of a court finding that a supplier of the tests acted negligently or breached its contract with the consumer and in order to comply with the provisions of the Act it is essential that the manufacturers/suppliers of the ST kits provide adequate warnings about the product and about the risk of false results.

6.9.1. We consider that it would be prudent to include the following:

- prominent warnings about the accuracy of the tests on the exterior packaging of the tests;
- a recommendation that users of the product seek counselling prior to using the ST kit and provide contact details of facilities where such counselling can be provided;
- comprehensive information and educational material about HIV and AIDS including facts about viral loads and treatment. It would be beneficial to also include details of additional resources where further information can be obtained.
- information regarding the chronic nature of AIDS, that it can be treated by antiretroviral medication and that such medication is available free of charge at government clinics. Details of clinics should be provided;
- detailed instructions on how to use the kit in order to provide the best chance of an accurate result;
- prominent warnings in the package insert making users aware of the possibility of false test results and the degree of accuracy of the test;
- a recommendation that users who suspect that the result may be false obtain a test by a medical professional to confirm the result of the ST kit and provide contact details of where such tests can be undertaken;
- a recommendation that users obtain counselling after using the ST kit and provide contact details of facilities where such counselling can be provided;
- an exclusion of liability in the case of false test results or any consequences arising from false test results.

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

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

Introduction

- 7.1.1. Written consent is preferable but not required. There must, however, be informed consent. There are exceptions to the requirement of consent (as per 5.3 above).
- 7.1.2. The GPP standards lay down certain minimum standards for the performance of HIV tests, which include that the:
- consent given must be specific and explicit; and
 - patient must at least be informed of the:
 - (a) reasons and purpose for the test;
 - (b) advantages and disadvantages of being tested;
 - (c) influence of the test on the patient's medical treatment;
 - (d) psycho-social impact the test may have on them;
 - (e) freedom to decline the test; and
 - (f) procedure.
- 7.1.3. Due to the exceptional nature of HIV/AIDS and the serious implications of a positive test, it is required that the patient consents to HIV testing specifically. An HIV test is not covered by general or implied consent, nor is there valid consent where a patient consents to blood being drawn for a series of tests, including an HIV test, without specifically being informed that the HIV test will be done.
- 7.1.4. The person consenting must be capable of consenting.
- 7.1.5. There is no legislative sanction provided for situations where an HIV test is performed without informed consent but it arguably constitutes an infringement of a person's:
- common law right to physical integrity and body; and
 - constitutional rights to human dignity, freedom and security of the person and privacy;

which would give the wronged person an action on a number of bases discussed below.

7.1.6. The general requirement for informed consent is limited in terms of the:

- Criminal Procedure Act 51 of 1977 which makes provision for police officials to obtain blood samples by force for the purpose of obtaining certain evidence; and
- Criminal Law (Sexual Offences and Related Matters) Amendment Act 32 of 2007 which allows the victim of a sexual offence, an interested person acting on behalf of the victim, or an investigating officer to apply for the compulsory HIV testing of an accused.

Delict

7.1.7. The South African law of delict is governed by the common law which is based on court decisions.

7.1.8. Physical integrity is recognised as being worthy of protection under the common law.

7.1.9. This right can be infringed by conduct causing physical pain, mental distress, shock, loss of life expectancy, loss of amenities of life, inconvenience and discomfort, disability or disfigurement.

7.1.10. In *PFG Building Glass (Pty) Limited v CEPPAWU 2003 (5) BLLR 475 (LC)*, which was ultimately decided on the basis that the performance of an HIV test without informed consent would automatically be prohibited under section 7(2) of the Employment Equity Act, it was stated that the right to physical integrity or body is enforceable under the *actio iniuriarum* (an action for the wrongful and intentional injury to bodily integrity of another). The court went on to say that although the content of the right to bodily integrity is the same under the common law as it is under the Constitution, the remedies and onus will differ.

7.1.11. In order to be liable under this action it must be shown that the:

- infringement is not trivial;
- infringement is wrongful; and
- medical practitioner acted with the intention to injure the patient's bodily integrity.

7.1.12. Although this judgment was decided in an employment context, the right to bodily integrity and the action which can be used to address injury to bodily integrity are not limited to that context and are of general application.

7.1.13. As far as triviality is concerned, in *Seetal v Pravitha 1983 (3) SA 827 (D)* it was held that performing a blood test on someone without their consent would amount to a serious invasion of privacy and the invasion is "no less such because on just about every occasion the test is otherwise innocuous".

7.1.14. Under the common law, the plaintiff must prove all the elements of a delict (act, fault (in the form of intention or negligence), wrongfulness, causation and damages).

7.1.15. In *Castell v De Greef 1994 (4) SA 408 (C)*, the court held that "consent by a patient to medical treatment is regarded as falling under the defence of voluntary assumption of risk which would justify an otherwise wrongful delictual act".

7.1.16. Therefore, it appears that where an HIV test is performed without the patient's consent, the practitioner administering the test could be liable in delict, the lack of consent going to the wrongfulness enquiry.

7.1.17. There has been some argument that the failure to obtain consent could be regarded as negligent conduct in that the medical practitioner breached a duty it owed to the patient by not fully informing them of the risks involved. However, the court in *Castell v De Greef* disapproved of this, saying that the issue is one of wrongfulness as opposed to negligence.

7.1.18. It is important to bear in mind, however, that both wrongfulness and negligence must be proved. The wrongfulness enquiry addresses whether conduct is contrary to public policy, while the negligence enquiry deals with whether the reasonable man would have foreseen a risk of harm materialising and taken steps to prevent it, but the person in that specific case failed to do so.

7.1.19. In *C v Minister of Correctional Services 1996 (4) SA 292 (T)*, the plaintiff had been subjected to an HIV test without having been informed of its purpose and had not received pre- or post-test counselling as required in terms of the Department of Correctional Services' policy. It was held that this was a "deviation from the accepted norm of informed consent" and, since it was a deviation to a significant degree, constituted wrongful conduct. Therefore, the court awarded the plaintiff damages under the *actio iniuriarum*.

- 7.1.20. This case shows that in order for a deviation to constitute wrongful conduct, it must be of a significant degree. Whether a particular deviation would be wrongful would depend on the legal convictions of the community.

The Constitution

- 7.1.21. The Constitution guarantees the right to:
- human dignity;
 - freedom and security of the person, which includes the right to bodily integrity and particularly, the right not to be subjected to medical or scientific experiments without their informed consent; and privacy.
- 7.1.22. Failure to obtain consent from a patient would be a breach of their constitutional rights.
- 7.1.23. Section 38 of the Constitution gives everyone the right to approach a court if they believe one (or more) of their constitutional rights have been infringed and allows a court to grant “appropriate relief”.
- 7.1.24. Under the Constitution, the mere infringement of a right gives rise to a remedy and the onus is on the wrongdoer to prove that the infringement is justifiable.

Contract

- 7.1.25. It has been suggested that a medical practitioner could be held liable on the basis of contract for failure to obtain informed consent before administering any form of medical test/treatment, although there is very limited authority dealing with this issue.
- 7.1.26. The failure to obtain consent could be viewed as a breach of a term of the contract.
- 7.1.27. This would, of course, depend on the contract between the patient and the medical practitioner.

Criminal

- 7.1.28. It has further been suggested that, in certain circumstances, a person could be guilty of a criminal offence if they perform medical procedures on a patient without informed consent, namely:
- assault; and
 - *crimen iniuria* (the crime of unlawfully, intentionally and seriously impairing the dignity of another).
- 7.1.29. However, these crimes tend to arise only in cases where there was a surgical intervention performed without consent which resulted in the death or injury of the patient.
- 7.1.30. In *Broude v McIntosh* 1998 (3) SA 60 (SCA) the court expressed doubt that lack of informed consent could give rise to an action for assault.
- 7.1.31. Furthermore, in order to be liable for *crimen iniuria* it has been held that the infringement needs to be reasonably serious and it is uncertain whether lack of consent in the context of HIV testing would be sufficiently serious to constitute a criminal offence on the part of the medical practitioner.

Conclusion

- 7.1.32. Although informed consent is required in terms of legislation, there is no particular legislative sanction provided for situations where an HIV test is performed without such consent.
- 7.1.33. Performing an HIV test without consent would constitute an infringement of a person's:
- common law right to physical integrity, body or *corpus*; and
 - *constitutional rights to human dignity, freedom and security of the person and privacy*.
- 7.1.34. This would give the wronged person an action under:
- the *actio iniuriarum in delict*, with the lack of consent going to the wrongfulness enquiry; and
 - *Section 38 of the Constitution which allows a person to approach a court if any of their rights have been infringed and for a court to award “appropriate relief”*.
- 7.1.35. There is also potential for liability in terms of:
- contract; and
 - criminal law;

although there is less authority dealing with them, and there has been some doubt as to whether there could be liability on these grounds.

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. In terms of section 130 of the Children's Act, 38 of 2005, a child can consent to an HIV test if it is:

- 12 years old or older; or
- Under the age of 12 years and has sufficient maturity to understand the benefits, risks and social implications of the test ("the implications").

7.2.2. If a child is under the age of 12 years and does not have sufficient maturity to understand the implications, the following people can consent:

- Parent or care-giver;
- Provincial head of social development; or
- A designated child protection organization arranging the placement of the child.

7.2.3. The superintendent or person in charge of a hospital can give consent if:

- The child is under the age of 12 years and does not have sufficient maturity to understand the implications; and
- There is no parent or care-giver and there is no designated child protection organization arranging the placement of the child.

7.2.4. A children's court can give consent if:

- Consent by the persons listed in 7.2.1 or 7.2.2 is unreasonably withheld; or
- The child or the parent or care-giver of the child is incapable of giving consent.

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

7.3.1. In terms of section 132 of the Children's Act, 38 of 2005, a child (under 18 years) may only be tested for HIV after proper counselling by an appropriately trained person, of:

- The child, if it has sufficient maturity to understand the implications; and
- The parent or care-giver, if the parent or care-giver knows of the test.

7.3.2. Post-test counselling is also required after the test, under the same circumstances.

7.3.3. An adult will be invited and encouraged to take part in pre- and post-test counselling, which is an element of informed consent, but may refuse.

7.3.4. The norm is to offer continued counselling and support to a person with a positive diagnosis.

7.4 Confidentiality of test results

7.4.1. In terms of section 133 of the Children's Act, 38 of 2005 a person may not disclose the fact that a child is HIV-positive without consent being given by the same persons allowed to give consent to the testing of the child (as per 6.2.1 to 6.2.4 above).

7.4.2. The exceptions are that it may be disclosed:

- Within a person's powers and duties in terms of the Children's Act, 38 of 2005 or any other law;
- Where necessary for purposes of carrying out the provisions of the Children's Act, 38 of 2005;
- For the purpose of legal proceedings;
- In terms of a court order.

7.4.3. There is no provision dealing with the disclosure of the fact that a person is HIV-negative, but it is submitted this would be governed by the Constitutional norms relating to the right to privacy.

7.4.4. See paragraph 5.3.2 regarding the confidentiality of test results between an employer and employee.

- 7.4.5. The results of an HIV test performed on an alleged offender in terms of the Criminal Law (Sexual Offences and Related Matters) Amendment Act, 32 of 2007 may only be communicated to:
- The victim or interested person;
 - The alleged offender;
 - The investigating officer;
 - Where applicable:
 - a) prosecutor;
 - b) any person who needs to know the results for purposes of civil proceedings or an order of court.
- 7.4.6. Other than that, Constitutional norms will apply.
- 7.4.7. See also 7.5 below.

7.5 Duties of disclosure to partner/employer/insurer

- 7.5.1. There is currently no obligation on an employee or anyone else to disclose the employee's HIV status to an employer, unless the employer has obtained an order from the Labour Court to compel testing (as per 5.3.2 above). Where the employee does disclose his/her status voluntarily, the employer must keep the disclosure confidential and may not disclose it to any other person without the employee's written consent. Practically, employees are encouraged to make confidential disclosures of their HIV status to their employers, as employers are legally obliged to provide reasonable accommodation to a person living with HIV and AIDS in order for them to access and enjoy equal employment opportunities.
- 7.5.2. One does not have a legal obligation to disclose one's status to one's partner, but perhaps a moral/ethical obligation. See 5.2.2 above regarding the duty of health care practitioners to disclose results to a partner. The Health Professions Council of South Africa: Ethical Guidelines for Good Practice with regard to HIV (May 2008) provides guidelines to health care practitioners on resolving the ethical dilemma they are faced with when an HIV positive person who refuses, despite counselling, to inform his/her partner of his/her status.
- 7.5.3. Insurance companies may request a proposer for life insurance to undergo an HIV test, as this may affect the assessment of someone's risk. A person can refuse, but this may mean that the insurance company does not offer cover. If the person allows the test and is HIV-positive, higher premiums or specific exclusions may apply. Having said that, in terms of the Promotion of Equality and Prevention of Unfair Discrimination Act, 4 of 2000, unfairly disadvantaging a person or persons, including unfairly and unreasonably refusing to grant services, to persons solely on the basis of HIV/AIDS status, is described as an unfair practice in the insurance sector. A proposer for insurance should not be dishonest on a proposal form. If the information is material and would have influenced either the granting of cover or the terms and/or conditions on which cover is provided, an insurer will be able to avoid the policy from inception.

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

- 8.1 In *S v Nyalungu* 2013 (2) SACR 99 (T), the court considered the conviction of a person who raped a woman whilst aware of his HIV status and not taking any preventative measures. The court, taking guidance from the South African Law Commission's Fifth Interim Report on Aspects of the Law Relating to AIDS and two Canadian cases, held that the principles of common law were wide enough to cover the situation where a virus was intentionally transferred to another person. Where someone is fully aware of their HIV status and, despite that knowledge, rapes a victim without using protective measures, he/she will be convicted of attempted murder. As long as the act was performed with the intention of bringing about a particular result (ie to transmit the HI-virus), an attempt is proven. It is not necessary for the victim to have been infected.
- 8.2 It is not sufficient to prove negligence. The person must have acted intentionally and, for a conviction to ensue, intention must be proved beyond reasonable doubt, which can be very difficult. There have, however, been a number of successful cases.

9. FURTHER INFORMATION

9.1 N/A.

10. REFERENCES

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