



Southern African AIDS Trust

REPORT

REGIONAL

2014

REVIEW

**MULTI-JURISDICTION REVIEW
OF THE 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.

Thomson Reuters Foundation brokered the relationships between SAT and 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.

¹ UNAIDS 2013; WHO 2013

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 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 consolidated report for multi-country findings.

The summary findings of this review are presented in this report. Detailed country specific findings are presented as stand-alone reports and are available at SAT on request as well as on the website www.satregional.org.

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

Jonathan Gunthorp



Executive Director - SAT



ACKNOWLEDGEMENTS

Southern African AIDS Trust (SAT) wishes to acknowledge individuals, organisations and law firms that contributed to this report through their, expertise, co-operation and hard work.

Our thanks go to all the firms and individuals that conducted the legal review pro bono`. These are: Arnold & Porter (UK) LLP, England, Arnold & Porter (US) LLP (United States of America), Corpus Legal Practitioners (Zambia), Dechert (France), Gill, Godlonton & Gerrans (Zimbabwe), Nexus Attorneys (Tanzania), Norton Rose (South Africa), Pimenta, Dionísio e Associado (Mozambique), Rantao Kewagamang Attorney (Botswana) and Savjani & Co (Malawi). Special thanks go to Arnold & Porter (UK) and in particular to Catherine Young for their coordinating role in the legal review in all the participating countries. We would also like to thank Thomson Reuters Foundation who brokered the relationship with the legal firms.

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

Last but certainly not the least, SAT is grateful to Wits Reproductive Health Institute for all the support and input during the HIVST Consultative Workshop.



DISCLAIMER

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MULTI-JURISDICTION REVIEW OF THE LEGAL ISSUES SURROUNDING THE DISTRIBUTION OF HIV SELF-TESTING KITS IN



BOTSWANA

ARNOLD & PORTER (UK) LLP

ENGLAND & WALES



FRANCE



MALAWI



MOZAMBIQUE



SOUTH AFRICA



TANZANIA

ARNOLD & PORTER LLP

UNITED STATES OF AMERICA



ZAMBIA



ZIMBABWE



THOMSON REUTERS
FOUNDATION

**PREPARED FOR
SOUTHERN AFRICAN AIDS TRUST
(SAT)
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1. Introduction/Background

- 1.1 SAT has engaged various firms on a pro bono basis to conduct a review of the laws relevant to HIV self-testing (“HIVST”) in a number of jurisdictions. These include the countries where SAT operates: Botswana, Malawi, Mozambique, South Africa, Tanzania, Zambia and Zimbabwe as well as the U.S.A., France and England. The firms who have participated in this project are:

Arnold & Porter (UK) LLP	England
Arnold & Porter (USA) LLP	United States of America
Corpus Legal Practitioners	Zambia
Dechert	France
Gill, Godlonton & Gerrans	Zimbabwe
Nexus Attorneys	Tanzania
Norton Rose	South Africa
Pimenta, Dionísio e Associados	Mozambique
Rantao Kewagamang Attorneys	Botswana
Savjani & Co	Malawi

The African country reports were prepared to inform SAT of the legal framework and human rights implications relevant to HIVST in those countries. The reports on jurisdictions outside Africa are intended to act as a comparative guide on the legal approach and standards these countries have adopted in relation to HIVST. The questions SAT has raised in this regard and which are addressed by the country reports are as follows:

- i) Is HIV self-testing legal and, if so, under what conditions?
- ii) What legislation governs the distribution of HIVST kits and what rules/conditions exist concerning this distribution?
- iii) What are the human rights issues surrounding HIVST?
 - a. Does every person have a right to be tested?
 - b. Can a person be compelled to make any disclosures concerning a positive diagnosis and, if so, in what circumstances?
 - c. Can a person be forced to take a test or compelled to have a child tested?
 - d. What is the law regarding discrimination based on a person’s diagnosis with HIV?
- iv) 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?
- v) Further issues concerning HIV regarding consent, counselling, disclosure and confidentiality
- vi) Duties of disclosure to partner/employer/insurer
- vii) What are the criminal implications of transmitting - or being reckless as to transmission of - HIV?

- 1.2 In the U.S.A., the answers to the above questions vary by state. Consequently, the report on the laws in the USA focuses on the policy and regulation of HIVST kits at the federal level.

- 1.3 Unless otherwise stated in the country reports, references to HIV self-testing (“HIVST”) refers to the unsupervised use of a diagnostic device that allows the user to ascertain his/her HIV status. These kits are distinct from mail-in kits where the sample is collected by the user in private but sent to a laboratory for testing and diagnosis.

2. Summary of advice

2.1 Below are summaries of the outcomes of the legal research on each question. In addition, a table summarising and consolidating the answers can be found on page 9.

2.2 Is HIV self-testing legal and, if so, under what conditions?

- 2.2.1 Jurisdictions outside Africa: HIVST is legal in both the USA and the UK but not in France. The UK lifted the prohibition on HIVST in April 2014. The French government has announced its intention to amend the law to allow HIV self-testing in private. For the time being rapid testing can only be conducted in France under the supervision of a qualified medical or social professional.
- 2.2.2 African jurisdictions: HIV testing in Tanzania and Botswana is restricted to approved HIV testing centres and testing can only be conducted under the supervision of a trained professional. Legislative change would be required prior to introducing HIVST kits for unsupervised home use in these jurisdictions.
- 2.2.3 HIVST is not prohibited in Malawi, Mozambique, South Africa, Zimbabwe and Zambia. Although there are no statutes that expressly permit HIVST in these jurisdictions there are legal uncertainties and policy considerations in some of these jurisdictions which need to be taken into account. For instance, pharmacies are prohibited from selling HIVST kits in South Africa, HIVST do not appear to be marketed in Mozambique, and the Ministry of Health in Zimbabwe does not currently allow them although it is considering changing its policy.

2.3 What legislation governs the distribution of HIVST kits and what rules/conditions exist concerning this distribution?

- 2.3.1 HIVST kits are diagnostic devices and as such are considered medical devices or medicines in many jurisdictions. Some jurisdictions regulate the distribution of medical devices and/or medicines so bringing these products to market requires compliance with specific rules. The US and the European Union ("EU") (of which the UK and France are members) have different ways of regulating medical devices and elements of these models can be seen in the systems in Mozambique, Tanzania, and Zambia. South Africa and Zimbabwe have legal frameworks for regulating medicines but do not presently regulate HIVST kits. Botswana is in the process of creating such laws and Malawi only has general product safety legislation which refers to compliance with Malawi standards.
- 2.3.2 Where a regulatory framework exists, the applicable conditions for marketing and distribution differ between jurisdictions. In the USA medical devices must be approved by the Food and Drug Administration before they can be placed on the market. Regulatory authorisations are also required in Tanzania and Mozambique. In the EU medical devices placed on the market must meet the "essential requirements" that apply to the product and bear a CE mark. Zambia also prohibits medical devices that do not meet prescribed standards of quality.
- 2.3.3 The USA is the only jurisdiction which currently has an authorised HIVST kit on the market. Despite the recent legalisation of HIV self-testing in the UK, HIVST kits are still not available due to the fact that there are no HIVST kits which conform with minimum European standards.

2.4 What are the human rights issues surrounding HIVST?

2.4.1 Does every person have a right to be tested?

- 2.4.1.1 Some countries restrict access to HIVST kits or prohibit HIVST but this may conflict with rights to HIV testing and/or healthcare.
- 2.4.1.2 Tanzania and France have enshrined a right to be tested for HIV in law. The Minister of Health in Botswana is legally obliged to provide HIV testing facilities to the public. A right to testing exists in Zambia, however, it is established under policy not law. Other countries have general rights of access to healthcare services which may or may not be interpreted as establishing a right to HIV testing (South Africa, Zimbabwe and Mozambique). Malawi and England do not have legal rights to HIV testing or healthcare but every person has access to healthcare services which includes HIV testing. In the USA there has been no express recognition of a Federal right to HIV-testing but state laws may provide otherwise.

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

2.4.2.1 In most jurisdictions there is no absolute right to privacy and there are circumstances when the results of tests can be disclosed without the person's consent. Mozambique and France do not allow for any exceptions to this right.

2.4.2.2 The laws in some jurisdictions describe specific situations when HIV test results may be disclosed (Botswana, Malawi, Tanzania, the USA and Zambia). England (under the European Convention of Human Rights), Zimbabwe and South Africa have a qualified right to privacy in that an HIV diagnosis may be disclosed if the disclosure is carried out in accordance with prescribed conditions. These conditions can include instances where there is an interference with the rights of others, and/or the disclosure is proportionate in the circumstances. In Zimbabwe, such an interference with the right to privacy must also be prescribed by law such as the law concerning the HIV status of persons convicted of sexual offences.

2.4.2.3 Depending on the jurisdiction exceptions tend to relate to:

- disclosures to partners;
- disclosures pursuant to a court order;
- disclosures to guardians/parents of minors or incapacitated individuals;
- test results of individuals suspected or convicted of a sexual offence; and,
- disclosures necessary for the provision of medical treatment.

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

2.4.3.1 HIV self-testing outside of a supervised setting may be used to test other individuals and minors. This could allow individuals to test others through co-ercion.

2.4.3.2 Consent is normally required before testing an individual (see paragraph 2.6.1) but exceptions to this rule exist in most jurisdictions. Circumstances where forced testing can take place legally include: persons suspected or convicted of committing a sexual offence; prison inmates; on the judgment of medical practitioners; in accordance with a court order; donor of blood/tissues; newborns; and, where the testing is in the public's interest. These exceptions can sometimes be extended to children where the parents refuse to consent on their behalf.

2.4.3.3 Zambia, France and England do not appear to allow for any exceptions to the rule on consent although in England there are cases where children have been tested against the parents' consent. In Zimbabwe the exception is limited to individuals accused of sexual offences.

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

2.4.4.1 All jurisdictions prohibit discrimination in one way or another. Prohibitions can derive from a number of sources such as general constitutional protections from unfair discrimination; to protections under employment law as well as statutory provisions which specifically protect individuals with HIV from discrimination.

2.4.4.2 Constitutional discrimination is usually a general prohibition that extends to HIV status by interpretation. Constitutional protections exist in Botswana, Malawi, Zimbabwe, Zambia (which also has employment laws) and, South Africa. A similar protection exists in the European Convention of Human Rights which applies to France and England. In addition to the ECHR, the French criminal code prohibits discrimination specifically against individuals with HIV and England's employment laws have provisions on discrimination. Tanzania has laws protecting HIV positive individuals in specific circumstances while the protections in Mozambique come from various legal sources including criminal law. In the USA discrimination on the basis of disability is prohibited under federal law and the U.S.'s highest court has held that HIV-infection is a disability.

2.5 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?

- 2.5.1 Individuals who distribute products including medical devices generally have certain obligations towards the users of their products. If they fail to comply with these duties they can be liable to the consumer for harm or damage their failure caused. Tanzania is a notable exception because in this jurisdiction product liability claims are directed at the agency which authorised the product for distribution (the Tanzania Food and Drug Authority) and not the supplier¹.
- 2.5.2 It is not possible to predict all the circumstances in which claims might be brought against the manufacturers or distributors of HIVST kits. Examples of the scenarios we envisage might be if a patient is misdiagnosed as HIV positive and suffers emotional stress. In these circumstances, family members who suffer may also want to bring a claim. Another situation would be when a patient is misdiagnosed as HIV negative and subsequently infects another person. In certain circumstances this third person may be able to sue the supplier for medical costs which have the potential to be substantial.
- 2.5.3 There are certain categories of liability regimes which are common to most countries and which are used by consumers to bring product liability claims against suppliers. These are:
- Contract law: usually a contract is created between the consumer and the retailer of a product under which the retailer has certain obligations relating to the quality of the product.
 - Delict: tends to apply when someone has been harmed or suffered damage as a result of someone else's negligent or reckless act or, in some countries, an omission to act.
 - Statutory product liability regimes: these laws are specifically designed to give consumers rights against suppliers who distribute sub-standard products.
- 2.5.4 All countries have one or all of the above categories of claims. The type of liability that applies to a supplier can impact on whether third parties and not just the patient can sue; the amount of compensation the claimant can receive; who in the supply chain the claimant can sue; and, what the claimant must demonstrate in order to prove the defendant is liable for his or her damages.
- 2.5.5 While it is not possible to eliminate the risks inherent with distributing a product such as an HIV self-testing kit there are ways to mitigate the risks. Consideration should be given to the extent to which this can be achieved via appropriate labelling.

2.6 Further issues concerning HIV regarding consent, counselling, disclosure and confidentiality

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

- 2.6.1.1 HIVST can be performed outside healthcare settings and it could be possible for someone to test another person using an HIVST kit or coerce another person to test themselves. These scenarios would raise issues of consent.
- 2.6.1.2 All jurisdictions require the patient's consent before an HIV test can be taken apart from the USA where the laws vary by State. Some specify that the consent must be informed and the patient must be capable of consenting. Consent can be written, conveyed verbally or indirectly expressed. None of the jurisdictions require consent to be given in a particular way apart from Tanzania where written consent from parents is required before testing minors. Where someone is incapable of consenting the laws may permit a medical practitioner to test the patient if it's in the patient's interest. In some cases consent to general medical care and treatment may be sufficient to encompass HIV testing.

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

- 2.6.2.1 The age of consent could have a bearing on the distribution of HIVST kits. Governments or suppliers may apply age restrictions on who can purchase or use the HIVST kit. Individuals who want to test children using HIVST would need to bear in mind the rules on consent for minors.
- 2.6.2.2 In most jurisdictions the age of consent is 16 years. Otherwise the age of consent is: 12 years in South Africa; 13 years in Malawi; and, 18 years in Tanzania and France. The age of consent in the USA varies between 14 and 18 years depending on the state in question. All jurisdictions require consent from the parent or guardian if the child is too young to consent for him/herself. In South Africa, the USA and England individuals below the age of consent do not require parent or guardian approval if they are deemed mature or competent enough to consent for themselves.

¹ Tanzania currently relies on the law of torts as there is no specific legislation dealing with product liability governing manufacturers' duties to consumers.

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

- 2.6.3.1 Counsellors are not normally present when an HIVST kit is used by a member of the public and there are concerns about the implications this may have. Bearing in mind that existing guidelines on counselling generally apply to HIV testing in health care settings, they may act as a guide as to the type of information that could be included in the product literature of an HIVST kit.
- 2.6.3.2 All countries offer counselling and the requirements differ per jurisdiction. Some don't have detailed guidelines such as Botswana and South Africa. In Tanzania pre and post-test counselling is a legal *condition* for the provision of testing in HIV testing centres. In some jurisdictions the aim of pre-test counselling is principally to ensure the patient can give informed consent. In France, pre-rapid test counselling must discuss the limits of expedited HIV-testing in terms of reliability. Post-test counselling can cover issues such as: partner notification; linkage to care; psycho-social support; the need for confirmatory testing if required; and, positive living. The topics covered may vary depending on whether the person's test result was HIV positive or negative.
- 2.6.4 Confidentiality of test results
 - 2.6.4.1 All countries protect their citizens' privacy but in different ways be it constitutional rights or statutory rights. General constitutional rights to privacy exist in Malawi, Mozambique, Zimbabwe and South Africa. Although these rights are not specific to HIV test results their scope may encompass such information. Specific laws protecting HIV test results exist in Mozambique, Botswana and Tanzania. In Zambia confidentiality of test results is protected as a matter of policy. Neither France nor England have laws which specifically protect the privacy of HIV test results but they have legal safeguards, including the ECHR, to protect confidential information such as HIV test results. The rules on confidentiality in the USA vary between states.
 - 2.6.4.2 As explained at paragraph 2.4.2 most countries permit exceptions to confidentiality protections.
- 2.6.5 Duties of disclosure to partner/employer/insurer
- 2.6.6 Individuals who are HIV positive may have legal duties of disclosure but, in the absence of adequate counselling, they may not be aware of these duties.

PARTNERS

- 2.6.6.1 Mozambique, Botswana, Tanzania and the USA have legal duties of disclosure. Zimbabwe has a duty on the basis that criminal liability for transmission could arise if the sexual partner is unaware that the other person is HIV positive. In England a duty of care may exist between partners under the tort of negligence, however, in some cases it may be possible to discharge the duty by avoiding sexual contact rather than disclosure. No duty of disclosure exist in the remaining jurisdictions. Nonetheless, in some countries such as Malawi and England provision is made for encouraging patients to disclose during counselling.

EMPLOYER

- 2.6.6.2 No jurisdiction places a duty of disclosure on an employee towards his or her employer. An exception exists in England and the USA for situations where the condition is relevant to the employee's ability to do the job.

INSURER

- 2.6.6.3 Individuals in Tanzania, Botswana, Malawi and Zambia are not obliged to disclose their HIV status to insurers. Mozambique, South Africa, Zimbabwe, England, France and the USA have duties of disclosure to insurers. Where a duty is not complied with the insurance contract can usually be revoked. Tanzanian and South African anti-discrimination laws may impede insurance companies from denying health insurance to someone on the basis of his/her HIV-positive status.

2.7 What are the criminal implications of transmitting - or being reckless as to transmission of - HIV?

- 2.7.1 Individuals who use HIVST to diagnose themselves in the absence of adequate counselling may not be aware of the criminal implications of transmitting HIV. Where a user of an HIVST kit is aware that the reliability of their negative test result is questionable, there may be scope, depending on the jurisdiction, to argue that the user could commit an offence of reckless/negligent transmission if s/he were to have unsafe sex without confirmatory testing.
- 2.7.2 Only Malawi and some states in the USA do not criminalise transmission of HIV. The test for criminal liability varies between the other countries, some only require deliberate or wilful transmission (South Africa, Tanzania, Zambia and France) while the others also criminalise reckless/negligent transmission (Botswana, Mozambique, England and Zimbabwe). Mozambique, Tanzania and Zimbabwe have created criminal offences which apply specifically to transmission of HIV. The other jurisdictions (South Africa, Zambia, France and England) extend the scope of existing criminal offences to cover certain situations where transmission of HIV occurs. Mozambique, Botswana and Zambia have offences for spreading HIV generally, not just by sexual transmission. Some jurisdictions increase applicable sanctions when HIV transmission occurs during the course of certain crimes (some states in the USA and Zimbabwe).

3. Further Information

3.1 During the HIV self-testing consultative workshop hosted by Southern African AIDS Trust on 25th-26th March 2014 participants raised additional issues that may be considered for further investigation:

- the impact of homosexuality on HIV transmission offences;
- compulsory testing in the military;
- polygamous relationships and duties of disclosure;
- parents' obligations and duties of care towards a child with HIV;
- triage of HIVST results and supplier liability; and,
- national validation of HIV tests and the type of HIVST kits e.g. finger prick vs oral swab, that may be distributed.

4. Summary of Country Reports

Question	Botswana	Malawi	Mozambique	South Africa	Tanzania	Zambia	Zimbabwe	France	England	USA ¹
1	Is HIV self-testing legal?	Yes ³	Uncertain ⁴	Yes ⁵	No ⁶	Yes ⁷	Yes ⁸	No ⁹	Yes ¹⁰	Yes ¹¹
2	(a) What legislation governs the distribution of HIVST kits?	The Public Health Act ¹²	Medicine Law Decree no. 22/99 of 4 May, 1999	Medicines and Related Substances Control Act, 101 of 1965, and the related Amendment Act, 72 of 2008	Tanzania Food, Drugs and Cosmetics Act of 2003	Medicine and Allied Substances Act No.3 of 2013	Medicines and Allied Substances Control Act [Chapter 15:03]	Decreets dated 28 May 2010 and 9 November 2010 ¹⁴	In-Vitro Diagnostic Directive, 98/79/EC Medical Devices Regulations 2002	Federal Food, Drug, and Cosmetic Act ¹⁵
	(b) What rules/conditions exist concerning this distribution of HIVST kits?	The sale of devices for HIV testing is restricted to representatives of approved institutions. ¹⁶	A business licence and prior authorisation from the Ministry of Health are required.	HIVST kits are not presently regulated.	Pre-Approval by the Tanzania Food and Drug Authority is required and the kits must be used in an approved laboratory.	A pharmaceutical license is required and medical devices must meet prescribed standards of quality.	HIVST kits are not presently regulated.	The devices must bear a CE mark. Rapid results HIVST can only be distributed for supervised use.	Medical devices placed on the market must meet the "essential requirements" that apply to the product and bear a CE mark.	Pre-market approval based on scientific evidence is required from the Food and Drug Administration.
3	The human rights issues surrounding HIV									
	(a) Does every person have a right to be tested?	Yes ¹⁷	Uncertain ¹⁹	Uncertain ²⁰	Yes ²¹	No ²²	Uncertain ²³	Yes ²⁴	No ²⁵	No ²⁶
	(b) Can a person be compelled to make any disclosures concerning a positive diagnosis?	Yes ²⁷	No	Yes ²⁹	Yes ³⁰	Yes ³¹	Yes ³²	No	No	Yes ³³
	(c) Can a person be forced to take a test?	Yes ³⁴	Yes ³⁶	Yes ³⁷	Yes ³⁸	No ³⁹	Yes ⁴⁰	No	No	Yes ⁴¹
	(d) Can a parent be compelled to have their children tested for HIV?	as above	as above	Yes ⁴²	as above	Yes ⁴³	Yes ⁴⁴	No	Yes ⁴⁵	Yes ⁴⁶
	(e) What is the law regarding discrimination based on a person's diagnosis with HIV?	The Constitutional right to freedom & equality protects all persons from discrimination, with some exceptions. ⁴⁷	Various laws prohibit discrimination both generally and in relation to HIV status. ⁴⁹	Various laws prohibit discrimination both generally and in relation to HIV status. ⁵⁰	Discrimination on the basis of a person's actual, perceived or suspected HIV and AIDS status is unlawful. ⁵¹	All persons are protected against discriminatory practices under the Constitution and employment law. ⁵²	The Constitution prohibits discrimination generally and a protection specific to HIV status exists under employment law. ⁵³	Discrimination on the basis of HIV status is a criminal offence. ⁵⁴	Discrimination generally is prohibited as is discrimination specifically on the basis of a disability such as HIV infection. ⁵⁵	Discrimination on the basis of a disability is prohibited ⁵⁶
4	If a kit is faulty/gives an inaccurate diagnosis, what is the liability of the supplier, to:									

Question	Botswana	Malawi	Mozambique	South Africa	Tanzania	Zambia	Zimbabwe	France	England	USA ¹
(a) The Patient: Tort/Delict Contract law Statutory consumer protection laws	✓ ✓ ✓ ⁵⁷	✓ ✓ ✓ ⁵⁷	✓ ⁵⁸ ✓ ⁵⁹	✓ ✓ ✓ ⁶⁰	Liability rests with the TFDA under tort ⁶¹	✓ ✓ ⁶² ✓ ⁶³	✓ ✓ ⁶⁴	✓ ✓	✓ ✓ ⁶⁵ ✓ ⁶⁶	State laws apply ⁶⁷
(b) Is the supplier liable to third parties?	Yes	Yes	Yes	Yes	N/A	Unlikely ⁶⁸	Yes, but not under contract law	Yes	Yes, but not under contract law	
(c) Is The answer different if a kit is supplied free of charge?	No ⁶⁹	No	Yes ⁷⁰	No	No	Yes ⁷¹	No ⁷²	No	Yes ⁷³	
5 Further issues concerning HIV										
(a) Must a person consent to HIV testing?	Yes	Yes	Yes	Yes ⁷⁶	Yes ⁷⁷	Yes ⁷⁸	Yes	Yes	Yes ⁷⁹	The rules vary by state ⁸⁰
(b) Does consent have to be in writing?	Not specified ⁷⁴	No	Not specified ⁷⁵	No	No	No	No	No	No	No ⁸¹
(c) What is the legal age to give consent?	16	13 ⁸²	16 ⁸³	12	18	16	16	18	16	14 - 18 years ⁸⁵
(d) What powers do parents/guardians hold in relation to consent process?	Parental consent required.	Parental consent required.	Parental consent required.	Younger minors can consent if deemed competent.	written consent from parents / Guardian required.	consent of a parent/guardian is required	Parent/guardian consent required.	Parents/guardians consent required. ⁸⁴	Younger children can give consent if deemed competent.	Powers vary by states ⁸⁶
(e) What are the rules/norms concerning the provision of counselling to those with a positive diagnosis?	Counselling is mandated but the information to be provided is not specified.	Pre and post-test counselling normally provided, counselling should encourage, HIV-positive persons to notify their partners.	Pre and post-test counselling is provided to: capacitate the user with knowledge on the risks of transmission, promote positive behaviours, and offer emotional support.	Counselling is required for testing of children. Adults are offered counselling but may refuse.	Pre and post-test counselling is a legal condition for the provision of testing in HIV testing centres.	Persons undergoing VCT must be made aware of their rights ⁸⁷ . Counseling is viewed as a means to initiate prevention and ensure access to continuing care	Several pre-test counselling sessions may be required. Post-test and follow-up counselling must be provided for both HIV positive and HIV negative persons.	A post-test consultation is required during which the limits of HIVST in terms of reliability must be explained.	Pre-test counselling establishes informed consent. Post-test counselling discusses: the stage of the disease, treatment, and partner notification.	The rules/norms vary by state ⁸⁸
(f) Are test results confidential?	Yes	Yes ⁸⁹	Yes	Yes ⁹⁰	Yes ⁹¹	Yes ⁹²	Yes ⁹³	Yes	Yes ⁹⁴	Yes ⁹⁵ (Federal and State laws apply)

Question	Botswana	Malawi	Mozambique	South Africa	Tanzania	Zambia	Zimbabwe	France	England	USA ¹
6	Does a person have to disclose their HIV status to their: Partner Employer Insurance provider	: No No No	: Yes No Yes ⁹⁶	: No No Yes	: Yes No ⁸⁷ No ⁸⁸	: No No No	: Yes No Yes ⁸⁹	: No No No ¹⁰⁰	: No Yes ¹⁰¹ Yes	State laws apply: Yes ¹⁰² No ¹⁰³ Yes ¹⁰⁴
7	Is it a criminal offence to transmit/attempt to transmit HIV?	No	Yes	Yes	Yes ¹⁰⁶	Yes ¹⁰⁷	Yes ¹⁰⁸	Yes	Yes ¹⁰⁹	Yes ¹¹⁰ (State laws apply)

5. Endnotes

- 1 The rules and laws relating to most of these topics consist of both state and federal laws and the legal position, therefore, varies across the country. Where possible we have answered the questions using the legal position adopted at the federal level, and in the absence of such laws we explain the position adopted in the majority of states. The answers provided do not give a full and accurate picture of the legal position across the USA.
- 2 Section 119 of the Public Health Act stipulates that HIV testing must be carried out in approved premises and Section 120 restricts the sale of HIV tests to recognised institutions.
- 3 There is no law that prohibits HIVST.
- 4 The Mozambican legislation is silent with regard to HIVST. Although there is no specific law relating to the distribution of self-testing kits, there is also no law prohibiting it.
- 5 HIVST is not prohibited
- 6 Section 3 of the HIV and AIDS (Prevention and Control) Act, 2008 defines "HIV testing" to mean "**any laboratory** procedure done on an individual to determine the presence or absence of HIV infection". Individuals who want to be tested for HIV have to go to authorized centers for HIV testing. HIV self-testing kits are legal in Tanzania as long as the patient uses the kit in an officially recognised testing center.
- 7 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.
- 8 HIV self-testing is not prohibited by Zimbabwean law.
- 9 HIVST is only authorized in specific circumstances and under medical or social worker supervision ("supervised" self-testing) - decree dated 28 May, 2010 and decree dated 9 November, 2010 - but the government is planning to legalise unsupervised self-testing.
- 10 The prohibition on HIVST was lifted in April 2014 and it is now legal.
- 11 There is no law prohibiting HIVST.
- 12 Botswana does not have laws specifically regulating medicines and medical devices. The country is in the process of creating such laws and is currently doing a bench-marking exercise.
- 13 This is a general law relating to consumers. Malawi does not have legislation specific to medicines or medical devices.
- 14 An HIVST for supervised use must be CE-marked - Article 2 of decree dated 28 May 2010.
- 15 Federal laws, including the Food, Drug, and Cosmetic Act, govern medical device distribution. Additionally, approximately 25 states have regulatory oversight programs for device distribution; regulations vary.
- 16 Section 120 of the Public Health Act. Although Botswana does not regulate medicines and medical devices, in practice, the government works with relevant professionals from the Botswana Health Profession Council to validate medical devices and ensure they are operated by people with relevant qualifications.
- 17 The Minister of Health is obliged to ensure that confidential HIV testing facilities are made available to the public.
- 18 Every person has access to health care services in Malawi which includes VCT but this is not specifically provided for in the law.
- 19 The Mozambican Constitution establishes the general right to health, comprised by the right to medical and sanitary assistance but there is no specific right to be tested.
- 20 The South African constitution affords everyone the right to access to health care services but this has not been interpreted to establish a right to free HIV testing.
- 21 Section 15(1) of the HIV and AIDS (Prevention and Control) Act, 2008 states that "every person residing in Tanzania may on his own motion volunteer to undergo HIV testing" and Section 15(5) states that "every person attending a health care facility shall be counselled and offered voluntary HIV testing."
- 22 There is a deliberate policy towards encouraging every person to be tested but this right is not expressly enshrined in any law.
- 23 The right to healthcare is enshrined in the new Constitution of Zimbabwe but it does not expressly include a right to be tested for HIV. The HTC guidelines state that every Zimbabwean has a right to know his or her HIV status but this does not have legal effect.
- 24 Anonymous and free HIV laboratory testing at the patient's request is authorised by law.
- 25 The public in England are entitled to access services available on the National Health Service which currently include HIV testing but there is no legal right to HIV testing.
- 26 In the USA there has been no express recognition of a Federal right to HIV-testing but state laws may provide otherwise.
- 27 Section 116 of the Public Health Act makes it mandatory for persons infected with HIV to disclose their status to their sexual contacts and care givers.
- 28 Healthcare providers can disclose a person's HIV status to his/her partner if the patient refuses to do so him/herself.
- 29 An HIV positive diagnosis cannot generally be disclosed without the person's consent unless this protection is superseded by another person's conflicting right. Known exceptions occur when the person is compelled to take an HIV test (see next question).
- 30 Disclosures are voluntary save for a High Court Order. A diagnosis may also be disclosed to a spouse or sexual partner or the parent/guardian of a child.
- 31 The law recognises circumstances where a breach of privacy would be justified: disclosure under compulsion of the law and sharing of information amongst medical professionals.
- 32 Section 302A(5)(i) of the Criminal Procedure and Evidence Act (Chapter 9:07) allows the HIV status of a person convicted of a sexual offence to be revealed.
- 33 Federal and State laws govern the protection of individuals' rights not to disclose HIV status, and also mandate disclosure in certain circumstances (e.g., notification to sexual partners of possible exposure to HIV).
- 34 Section 104 (2) 3b empowers the Director of Health Services or his delegate to apply for an Order from a magistrate to compel a person to undergo an HIV test. The circumstances the Magistrate must take into account are prescribed in the Act and the Order may only be granted if it is in the public's interest. Medical practitioners may test a patient if he/she is unconscious and unable to consent and it is in the patient's interests. A person convicted of certain sexual offences are required to undergo testing.
- 35 HIV testing can take place without consent in the following situations: (i) where a person has difficulty making an informed decision to have an HIV test and where an HIV infections is suspected; (2) in screening of pregnant women; (3) where the testing is for transfusion and transplants.
- 36 The exceptions to the requirement to obtain prior consent are: when the practitioner deems an HIV test necessary exclusively for the patient's health and treatment; the test is related to blood or blood components, maternal milk, organs and human tissues donations; or, the tests are required for criminal proceedings/investigations, provided that there is a prior judicial ruling in this regard.

Endnotes (cont)

- 37 Testing without consent may take place in the following circumstances: an employer may make application to the Labour Court to allow the limitation of the right to privacy; or, individuals accused of a crime may, in certain circumstances, be tested compulsorily.
- 38 Testing is voluntary unless it is: under an order of the court; on the donor of human organs and tissues; or on sexual offenders. A medical practitioner may test a person without his/her consent if the person is unconscious and the test is in the interests of the patient.
- 39 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. However, there is no specific legislation which addresses this issue.
- 40 When the person is accused of a sexual offence.
- 41 Federal and varying State laws govern mandatory testing. Mandatory HIV testing includes blood and organ donors and military personnel and, in certain circumstances, persons accused of sexual crimes, newborns, and prison inmates. In certain cases, HIV testing may be offered as opt-out instead of opt-in. Opt-out testing means the test is done unless the patient explicitly refuses.
- 42 If the parents are deemed to unreasonably withhold consent
- 43 Mandatory testing should only be done in the best interest of the child and without any form of coercion from the counselor.
- 44 A child may be tested against the wishes of its parents if it is in his/her best interest.
- 45 A child may be tested against the wishes of its parents if it is in his/her interest.
- 46 Yes, minors can sometimes be tested against their parents' wishes. Many states authorize minors to make decisions about their own medical care, especially in the context of HIV testing.
- 47 Equality and freedom from discrimination are 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.
- 48 Under section 20 of the Malawi Constitution discrimination of persons in any form is prohibited. Although the Constitution does not specifically refer to discrimination on the basis of a person's HIV status one can argue that the words "other status or condition" may include a person's HIV status.
- 49 Various legislation prohibits discrimination based on a person's diagnosis with HIV including: the constitution; employment law; and, the law on the Rights and Duties of the Persons Living with HIV and AIDS.
- 50 Various legislation prohibits discrimination based on a person's diagnosis with HIV including: the Constitution; the Promotion of Equality and Prevention of Unfair Discrimination Act, 4 of 2000; and, the Employment Equity Act.
- 51 The HIV and Aids (Prevention and Control) Act, 2008 prohibits discrimination on the basis of a person's actual, perceived or suspected HIV and AIDS status in terms of: access to healthcare services; formulation or enactment of any laws and policies; admission or participation into services; travel restrictions; employment opportunities; accommodation; right of residency; and, any manner of stigmatization or discrimination.
- 52 While the laws on discrimination do not specifically reference HIV and AIDS, they may be utilized to protect the rights of people living with HIV. However, discrimination based on HIV status is specifically prohibited in citizen empowered companies.
- 53 Section 5 of the Labour Act [Chapter 28:01] specifically provides protection for employees against discrimination based on their HIV/AIDS status. Outside of the labour context, Section 56(3) of the Constitution of Zimbabwe ensures everyone has a right against unfair discrimination. It does not specifically mention HIV status but HIV may fall under "disability" or "social status" or may be regarded as an analogous ground.
- 54 In France, pursuant to article 225-1 of French Criminal Code, it is unlawful – in particular, for employers – to discriminate individuals on the basis of their serological status. Nevertheless, insurers are not obliged to provide coverage.
- 55 Article 14 of the European Convention of Human Rights contains a prohibition against discrimination in the context of another ECHR right. Article 14 has been found to include discrimination on the basis of a person's HIV status. Further, HIV infection is listed as a disability under the Equality Act and discrimination on the basis of a disability is unlawful.
- 56 Federal and State laws govern discrimination issues. Notable Federal laws include the Federal Americans with Disabilities Act ("ADA"), which prohibits discrimination on the basis of disability. The U.S.'s highest court has held that HIV-infection is a disability under the ADA.
- 57 Consumer Protection Act
- 58 The Mozambican Civil Code
- 59 The Consumer Defence Act
- 60 Consumer Protection Act
- 61 If the kits are approved by the TFDA the supplier is not liable towards individuals who use the kits or third parties and liability rests with the TFDA.
- 62 Sale of Goods Act
- 63 Medicines and Allied Substances Act, Foods and Drugs Act and the Competition and Consumer Protection Act
- 64 Common law and Consumer Contracts Act
- 65 Sale of Goods Act 1979 and Supply of Goods and Services Act 1982
- 66 Consumer Protection Act 198
- 67 State laws, including consumer protection and products liability laws, are implicated and payment is not an essential prerequisite to all liability. Additionally, in certain liability regimes third parties may have a right of action against suppliers.
- 68 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.
- 69 The claimant would need to establish a nexus for their loss/damage and the supplier's negligence.
- 70 Liability will arise if the supplier undertook responsibility.
- 71 Only tort applies
- 72 Depending on the circumstances contract law may not apply.
- 73 Only the common law tort of negligence applies. Depending on the circumstances statutory liability under the Consumer Protection Act may apply.
- 74 The form of consent required is not specified.
- 75 The form of consent required is not specified, but most private clinics require written consent.

Endnotes (cont)

- 76 Consent is required unless a court orders otherwise.
- 77 Consent must be informed i.e. the persons agreed to the procedure based on full information.
- 78 Informed consent required.
- 79 Consent is required except where a court orders that a child be tested, contrary to the parent's intentions
- 80 See the following websites for information on HIV State laws: <http://www.cdc.gov/hiv/policies/law/states/index.html>; and, <http://www.hivlawandpolicy.org/sites/www.hivlawandpolicy.org/files/2011%20UCSF%20Quick%20Reference%20Guide%20on%20HIV%20Testing%20Laws.pdf>
- 81 The U.S. Centers for Disease Control and Prevention does not recommend separate written consent for HIV testing beyond general informed consent for medical care notifying the patient that an HIV test will be performed unless the patient declines. Currently, most states have laws consistent with CDC recommendations.
- 82 16 is the legal age of majority but children aged 13 and over are entitled to access voluntary testing and counselling without the consent of a guardian or other adult.
- 83 A person is technically deemed a minor until 21 but minors between 16 and 21 can give consent.
- 84 Healthcare professionals are supposed to consult individuals under 18 even though it is their legal representatives who can make the final decision – Article L. 1111-4 of the French Public Health Code
- 85 Generally, state laws govern age of consent and range between 14 and 18 years of age. Note, however, that capacity to consent is not based on age alone, but an individual's ability to understand and appreciate the consequences of his/her decisions (often as adjudicated by a court of law or other state officials).
- 86 All of the states have specific laws regarding minors consenting to HIV testing. Certain states, however, permit physicians to notify parents of their child's HIV test results.
- 87 The rights are: right to privacy; non-discrimination; right to have a family; right to the highest attainable standard of physical and mental health; right to informed consent
- 88 States have various laws regarding counselling. For more information see <http://www.cdc.gov/hiv/policies/law/states/index.html>; and <http://www.hivlawandpolicy.org/sites/www.hivlawandpolicy.org/files/2011%20UCSF%20Quick%20Reference%20Guide%20on%20HIV%20Testing%20Laws.pdf>
- 89 Constitutional right to privacy
- 90 A person's HIV status is protected by the constitutional right to privacy but this may be qualified if it interferes with the rights of others.
- 91 The results of an HIV test shall be confidential and shall be released only to the person tested.
- 92 The right to privacy of a person enjoys constitutional protection..
- 93 Constitutional right to privacy
- 94 Various laws protect private information in different settings, these include: the ECHR right to privacy, the Personal Data Protection Act 1998, statutes to protect medical records of STI patients, and the common law duty of confidence.
- 95 Federal laws protect medical records in healthcare settings. Varying State laws govern the rules on confidentiality in other circumstances.
- 96 Pursuant to Law no. 1/2010 of 31 December, 2010 (which approves the Insurance Legal Framework) the parties are subject to an information duty. With reference to the policy holder, such duty implies that he/she needs to provide the insurance company with all information and facts that he/she may or should be aware of, which may influence the insurance company's assessment of the risk.
- 97 The employer may require a candidate to undergo a medical check-up but the fact that he/she is HIV positive would remain confidential between the doctor and the patient.
- 98 No duty exists but a medical insurance provider shall facilitate access to health care services to persons living with HIV and AIDS without discrimination on the basis of their status.
- 99 There is a duty to disclose to an insurer every fact or circumstances that would materially affect the calculation of the risk insured or the decision whether or not to enter into, renew, vary or reinstate an insurance policy.
- 100 If it can be evidenced that the patient has provided false information to the insurer, then the latter can consider that the insurance contract is not valid - Article L.113-8 of French Insurance Code.
- ¹⁰¹ Yes, in limited circumstances.
- ¹⁰² Many states mandate notification of sexual partners and needle-sharing partners of possible exposure to HIV, commonly called "partner notification" laws.
- ¹⁰³ Generally, an individual is under no legal obligation to disclose his/her HIV-status to his/her employer unless it affects his/her ability to perform the job.
- ¹⁰⁴ If an insurer has the right to ask (depends on the type of insurance), individuals must provide truthful answers.
- ¹⁰⁵ 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.
- ¹⁰⁶ Section 47 of the Act states that "Any person who intentionally transmits HIV to another person commits an offence, and on conviction shall be liable to imprisonment for a term of not less than five years and not exceeding ten years".
- ¹⁰⁷ Willful transmission is an offence. The penalty is determined depending on the offence for which the perpetrator is convicted of.
- ¹⁰⁸ Deliberate or reckless transmission of HIV is an offence.
- ¹⁰⁹ No legislation specifically criminalises HIV transmission but prosecutions for reckless, intentional or attempted intentional transmission of HIV can be brought under certain offences against the person.
- ¹¹⁰ More than half the States criminalize transmission of HIV. See <http://projects.propublica.org/tables/penalties> Some States provide for sentencing enhancement for sexual offenses involving risk of exposure to HIV.



Southern African AIDS Trust

REPORT

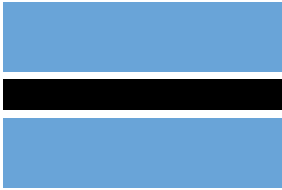
REGIONAL

2014



REVIEW - BOTSWANA

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



BOTSWANA

BOTSWANA

RANTAO KEWAGAMANG 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)a) Whether another person is or has been exposed to the possibility of transmission of HIV
 - b)b) The right to information of the person exposed to the possibility of transmission of HIV
 - c)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)a) Whether, and by what method, the person transmitted HIV;
 - b)b) The seriousness of the risk of the person infecting other persons;
 - c)c) The past behaviour and likely future behaviour of the person;
 - d)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

REPORT

REGIONAL

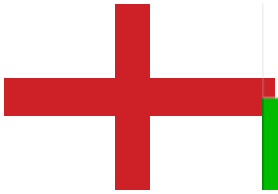
2014



REVIEW - ENGLAND & WALES



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



ENGLAND & WALES

ENGLAND & WALES

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1. Introduction/Background

- 1.1 The United Kingdom is divided into three legal jurisdictions, each with its own courts system: England & Wales, Scotland, and Northern Ireland. Some legislative powers have been devolved to the regional authorities. Consequently, the application of legislation passed by the UK parliament and the case law concerning common law principles can vary across the country. Our competence to advise on UK laws is limited to England & Wales which is a common law jurisdiction.
- 1.2 Another source of applicable laws is the European Union of which the United Kingdom is a member along with various other European countries. The competence of the European Union to issue rules is restricted to particular subjects. Legislation exists on the distribution of medicines and product liability but not the provision of healthcare within the member states. Some of the legislation discussed below implements EU law in the UK.
- 1.3 The UK recently legalised the distribution of HIV self-testing kits within its jurisdiction. As expected, we have not come across any case law concerning HIV self-testing kits (or self-testing kits of any kind) but there are a considerable number of cases, especially from the European Court of Human Rights, relating to HIV positive individuals. The following memo provides an overview of the legal regime and available guidance applicable in England & Wales to each topic.

2. Summary of advice

2.1 Legality of HIVST

The UK lifted the prohibition on HIV self-testing within its jurisdiction in April 2014.

2.2 Distribution

Regulation of the manufacture and distribution of self-testing kits is governed by both Directive 98/79/EC on in vitro diagnostic medical devices (European law) and the Medical Devices Regulations 2002 (UK law). The UK Regulations implement the European law. Before an in vitro diagnostic medical device, which includes HIVST kits, can be placed on the market, the manufacturer must ensure that the device meets the “essential requirements” - the specific requirements set out in the legislation for that category of device which seek to ensure that the device does not compromise the health and safety of patients and users. In addition, for certain high risk devices, including HIV detection devices, the assessment of compliance with these requirements must be overseen by a notified body (an independent certification organisation). Following this assessment, the manufacturer of the device may affix a “CE mark” to the device to show that it has undergone proper conformity assessment in accordance with the essential requirements, and which allows the device to be placed on the market anywhere in the European Economic Area.

2.3 Human Rights

- 2.3.1 **Right to testing:** HIV testing is available on the National Health Service in the UK, but there is no right to be tested as a human right. Case law from the European Court of Human Rights demonstrates that signatories to the European Convention of Human Rights are not under an obligation to provide individuals with healthcare but if a framework is in place it must operate in accordance with the principles contained in the Convention (e.g. non-discrimination).
- 2.3.2 **Disclosures:** Private information such as a person's HIV status is protected by Article 8 of the European Convention of Human Rights. The case law demonstrates that disclosures of a person's HIV status (without his/her consent) can be justified only if it is reasonable and necessary in the public interest; and, the extent of the disclosure does not exceed what is needed to meet the legitimate aim.

2.3.3 Compelled to be tested: An adult cannot be compelled to take an HIV test in England and Wales if they do not want to. There is a presumption that the parents' views as to what is in their child's best interest is to be respected. However, if a child is likely to suffer significant harm, the court may grant shared parental responsibility to a local authority who may make arrangements for - and give consent to - testing and treatment. In appropriate cases the court may step in and grant permission to test a child for HIV, contrary to the wishes of the child's parents.

2.3.4 Discrimination: Article 14 of the European Convention of Human Rights contains a prohibition against discrimination where there is no objective or reasonable justification for treating that person differently. If a person feels that a violation of their human rights has not been acknowledged by the national courts, that person may apply to the European Court of Human Rights. On several occasions, the Court has held that persons have been wrongfully discriminated against based on their HIV diagnosis. The UK Equality Act 2010 also prohibits discrimination on the grounds of a number of "protected characteristics", including disability (HIV is considered a disability for the purposes of the Equality Act in the UK). As more is learnt about HIV - and as more effective medication is developed - the UK has started to relax its laws that restrict the activities of those with HIV (on what were previously considered justified grounds). For example, gay men can now donate blood if they have not been sexually active for 12 months (and if they do not test positive for HIV). The law is also set to change to allow doctors and clinicians with HIV to perform certain procedures that were previously prohibited.

2.4 Liability

There are three liability regimes for personal injury that are likely to apply in the distribution of HIVST: the law of negligence, contract law, and the Consumer Protection Act 1987 (the "CPA"). Products that are distributed free of charge are subject to the law of negligence and the CPA while products that are sold to the consumer will also be subject to contract law. The CPA will not apply when the product was placed on the market outside the course of a business and when there was no intention to make a profit (regardless of whether it was distributed freely or sold to the consumer). The fact that a charity is supplying the product may not be sufficient evidence to rely on this exception. Liability between these three regimes differs. Third party liability for personal injury can arise under negligence and the CPA, but not under contract law. A defendant must have acted without reasonable care in order to be liable under negligence principles. In contract law the claimant must show that the defendant breached the terms of the contract and damage flowed from the breach. The CPA, however, is a strict liability regime and fault on the part of the defendant does not need to be established if the product was defective and caused personal injury.

2.5 Consent

A patient cannot be tested for HIV unless they have given valid consent (written consent is not necessary). There are a few exceptions to this general rule but such exceptions must be justified in accordance with the European Convention of Human Rights. A youth is presumed to have competence to consent to medical procedures from the age of 16. However, a child under the age of 16 may consent to a test if they can demonstrate that they have the maturity and intelligence to understand the test, the options, the risks involved and the benefits of that test.

2.6 Counselling

Pre-test discussions are encouraged so that a person understands the implications of the test and so that they can provide their informed consent to testing. It is encouraged that results are provided in person, particularly where a person tests positive. It is also considered best practise for those who test positive to have a meeting with a specialist within 48 hours.

2.7 Disclosure

There are no obligations to disclose the results of HIV tests to a partner or an employer. The fact that someone is HIV positive will be considered material information for the purposes of a health insurance contract and should be disclosed to the insurer during pre-contractual negotiations.

2.8 Criminal prosecutions related to HIV

There are three offences that a person can be charged with in England and Wales. These are reckless transmission, intentional transmission and attempted intentional transmission. A person cannot recklessly attempt to transmit HIV in England, although we understand the position may be different in Scotland. Twenty cases have reached the courts. There have not been any successful prosecutions for intentional transmission, presumably because of the difficulty in proving a defendant's intention to transmit HIV. Thirteen individuals have pleaded guilty and the sentences have ranged between 1 year and 4.5 years.

3. Is HIV self-testing legal and, if so, under what conditions?

- 3.1 As of 6 April 2014 HIV self-testing kits are legal in England, Scotland and Wales. In spite of the change in the law no kits are currently on the market because they currently fall short of the minimum standards specified by European guidelines.
- 3.2 The Health and Medicines Act 1988 allows the UK Government to regulate the trade in HIV testing kits and services.¹ The Government exercised this power in 1992 and limited dealings in HIV testing kits through the HIV Testing Kits and Services Regulations 1992 (the “HIV Regulations”). The HIV Regulations placed a ban on the sale of HIV home testing kits and the sale, supply, or advertising of HIV testing kits to members of the public was an offence. Similarly, the provision of HIV testing services was an offence unless it was by a registered medical practitioner or under such a person’s direction.² Despite the ban on HIVST kits, in the past they could be acquired over the internet³ and it may still be possible to purchase non-compliant kits in this way.
- 3.3 The government’s Office of Science and Innovation issued a Foresight⁴ report in 2006 on the future of detection, identification and monitoring systems for infectious diseases.⁵ The report took into account an analysis on the development of mobile diagnostic devices and their potential for tackling infectious diseases including HIV.⁶ With regard to sexually transmitted diseases, the report found that the health economic benefits for a widely available and cheap self-diagnostic device could be substantial. The report notes that detection, identification and monitoring systems ‘only provide information, and therefore will only yield benefit when linked to timely and effective disease management measures...’
- 3.4 On 1 September 2011, a Select Committee of the House of Lords published a report on HIV and AIDS in the United Kingdom entitled “No vaccine, no cure: HIV and AIDS in the United Kingdom”. The Paper showed the developments in HIV treatment in the UK, as well as making recommendations for future government policies. The issues discussed included, *inter alia*, the illegality of self-testing kits. The proposal from the Select Committee read as follows:
- The ban on HIV home testing kits, as laid out in the HIV Testing Kits and Services Regulations 1992, is unsustainable and should be repealed. A plan should be drawn up, in consultation with clinicians, patients, voluntary organisations and professional associations, to license kits for sale with appropriate quality control procedures in place. The licensing regime must make sure that the tests are accurate, and that the process gives comprehensive advice on how to access clinical and support services in order that those who test positive get the care that they need.*⁷
- 3.5 In October 2011, the Secretary of State for Health presented, to the English Parliament, the Government Response to the Select Committee Paper. On the issue of self-testing kits, the Government supported the recommendation and, as a result, the Department of Health stated its intention to review the policies governing HIV self-testing.⁸
- 3.6 In August 2013, the Department of Health released a statement on its plans for the modernisation of HIV rules.⁹ Amongst the most significant changes announced by the UK’s Chief Medical Officer were the fact that people will be able to buy self-testing kits for HIV, once those kits comply with applicable regulations.
- 3.7 In September 2013 the Department of Health issued a report on an audit of the impact of the Department’s Regulations upon business¹⁰. The audit found that the Regulation banning the sale of HIV self-testing kits was estimated as being of great cost to business with no positive wider benefit. The report refers to the Department’s plans to hold a limited stakeholder consultation on the plans to lift the prohibition but we have not established whether or not this took place.
- 3.8 The prohibition on the supply of self-testing kits was lifted on 6 April 2014 when the HIV Testing Kits and Services Regulations 1992 were repealed¹¹. Public Health England has issued answers to frequently asked

1 Section 23 Health and Medicines Act 1988

2 Regulations 2, 4 and 5 of HIV Testing Kits and Services Regulations 1992

3 MHRA press release, ‘Regulator warns against purchasing all HIV and non-compliant self-test kits over the internet’ 26 October 2011

4 Foresight projects use ‘the latest scientific evidence and futures analysis to address complex issues and provide strategic options for policy.’

5 Barker, I., Brownlie, J., Peckham, C., Pickett, J., Stewart, W., Waage, J., Wilson, P., and Woolhouse, M. (2006) Foresight. ‘Infectious Diseases: preparing for the future. A Vision of Future Detection, Identification and Monitoring Systems.’ Office of Science and Innovation, London

6 Various authors, ‘D2.3: User Challenge 3 - Taking technology for identification and characterisation of infectious diseases to individuals by designing smart swabs, hand-held or portable devices that analyse fluids’ Foresight. ‘Infectious Diseases: preparing for the future.’ Office of Science and Innovation, April 2006

7 House of Lords Select Committee on HIV and AIDS in the United Kingdom: 1st Report of Session 2010–12, No vaccine, no cure: HIV and AIDS in the United Kingdom, ¶ 214

8 Government Response to the House of Lords Report of Session 2010-12: No vaccine, no cure: HIV and AIDS in the United Kingdom, October 2011

9 <https://www.gov.uk/government/news/modernisation-of-hiv-rules-to-better-protect-public>

10 Department of Health, Final Report: An Audit of the impact of the Department of Health’s Regulations upon business, September 2013

11 The HIV Testing Kits and Services (Revocation) (England) Regulations 2014 No. 451

questions on HIV testing and self-testing¹² which explains that there are three main reasons why the ban on HIV self-tests was removed: increased access to HIV testing, treatment and care; regulation of self-test quality; and, public opinion on self-testing for HIV. Public Health England states that making self-testing available in the UK provides an 'additional testing method to reach out to those who are uncomfortable or unable to take an HIV test in a clinic'. They also note that medical devices such as HIVST kits must meet specific quality standards which ensures the quality and accuracy of self-testing kits. They also refer to positive experiences of users of HIVST kits in countries where these kits are already available.

- 3.9 In terms of monitoring the use of HIVST in the UK the government plans to use both established and new systems¹³. The Medicines and Healthcare products Regulatory Agency ("MHRA") is responsible for monitoring the safety of medical devices and HIVST kit users will report to the MHRA any incidents that cause unexpected or unwanted effects such as a misdiagnosis leading to inappropriate treatment. In addition, the outcome of reactive HIVST will be monitored through Public Health England in collaboration with the British Association for Sexual Health and HIV and the British HIV Association. Clinicians will be asked to report the confirmed HIV status of patients who have attended clinics for confirmatory laboratory testing following a reactive HIVST. All data collected will be anonymous.
- 3.10 HIV self-testing kits that are placed on the market must comply with applicable rules such as those governing the safety and distribution of medical devices. These rules stipulate that HIV self-testing kits comply with minimum standards and bear a CE mark of conformity (see section 4 for more information). At the moment, there are no kits currently on the market because existing kits do not meet the minimum standards set out under European guidelines¹⁴. The government expects this will change in 2014/15¹⁵.
- 3.11 When self-testing kits are introduced, if a test indicates a positive result, a person will still be advised to get a follow-up confirmatory test at an NHS clinic. Clear information on how to interpret the result and what to do afterwards will be included in the kits. Public Health Minister, Anna Soubry was quoted saying:
- 3.11.1 "HIV continues to be a serious health issue but we know that for a number of reasons some people are reluctant to come forward and get an HIV test in person.
- 3.11.2 By removing the ban on the sale of self-testing kits and cutting red tape that stops healthcare workers from treating patients we are bringing the UK in line with most other Western countries. We want to make it even easier for people to test themselves as early as possible and get the best treatment available"¹⁶

4. What legislation governs the distribution of HIVST kits and what rules/conditions exist concerning this distribution?

- 4.1 The manufacture and distribution for HIVST kits will be regulated by Directive 98/79/EC, the In-Vitro Diagnostic Directive ("IVD Directive"). The IVD Directive currently covers medical devices for the detection of HIV used by medical professionals. The requirements are harmonised across Europe, and the EU legislation has been implemented in the UK by the Medical Devices Regulations 2002 ("MD Regulations"), which refer directly to the EU legislation.
- 4.2 Note that each Member State has a competent authority responsible for implementing the requirements of the IVD Directive (as well as the Directives relating to other medical devices). However, the competent authority's main role is one of post-market surveillance and enforcement, and they do not approve devices before they are placed on the market.
- 4.3 We provide below an overview of the MD Regulations in the UK. It is possible that specific requirements for HIV self testing kits will be introduced, particularly in relation to information to be provided to the user, although the government has not, to our knowledge, announced any such plans.

The regulation of in vitro diagnostic medical devices

- 4.4 An *in vitro* diagnostic device ("IVD") is classified as a device made to analyse human body fluids, such as blood or urine, in order to provide critical information for diagnosing, preventing and treating diseases.¹⁷ Both the MD Regulations and the IVD Directive place the obligation on manufacturers to ensure that the medical devices they place on the market meet the "essential requirements" that apply to the product as

12 Public Health England, 'HIV Testing and Self-Testing: Answers to frequently asked questions' April 2014, http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317141025695

13 Public Health England, 'HIV Testing and Self-Testing: Answers to frequently asked questions' April 2014, http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317141025695

14 P. Stephens 'UK law passes sales of HIV home tests before they exist', 6 April 2014, BBC online, <http://www.bbc.co.uk/news/health-26888272>

15 Public Health England - HIV Testing, <http://www.hpa.org.uk/hivtesting> accessed on 16 April 2014

16 Press Release, Department of Health 'Modernisation of HIV rules to better protect the public', 15 August 2013

17 The precise definition is at Directive 98/79/EEC Art. 1(2)(b), MD Regulations Reg. 2.

set out in Annex I of the IVD Directive,¹⁸ and to follow the appropriate conformity assessment procedure to show compliance (which, for high risk devices such as HIV testing devices, must be with the involvement of an independent notified body¹⁹). The method and complexity of a device's assessment depends on the risk level of that device. A manufacturer is defined in the IVD Directive, Art 1(2)(f) as:

"... the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of [the IVDD] to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name ...".

4.5 All devices placed on the EU market, whether used in private or public hospitals and nursing homes or sold in retail outlets, must carry a CE mark to show that the device has undergone proper assessment in conformity with these requirements; once the manufacturer has verified that the IVD conforms with the IVD Directive, it may apply the CE mark to the IVD and distribute it. The CE marking enables free movement of the device within the European Economic Area (the EU as well as, Norway, Iceland and Liechtenstein) without the need for further approvals in each country. In addition, once an IVD bears a CE mark, Member States cannot create an obstacle to placing the IVD on the market.²⁰

The essential requirements

4.6 The IVD Directive includes "essential requirements" with which IVDs must comply before being placed on the market. The purpose of the essential requirements is to ensure that medical devices placed on the market do not compromise the health and safety of patients and users. Not all of the essential requirements will apply to all devices; the manufacturer of the device must assess which are appropriate for his product, taking into account the intended purpose.

4.7 The essential requirements for IVDs are grouped according to the following themes, and there are a number of specifications listed under each category:

- chemical and physical properties;
- infection and microbial contamination;
- manufacturing and environmental properties;
- requirements relating to devices with a measuring function;
- protection against radiation;
- requirements for medical devices connected to or equipped with an energy source;
- requirements for devices for self-testing; and
- information supplied by the manufacturer (including information for the user/instructions for use and information for the label).

4.8 In the MD Regulations, 'device for self-testing' means an "in vitro diagnostic medical device which is intended by its manufacturer to be able to be used by a member of the public in a home environment". The specific requirements on self testing kits in the Annex to the IVD Directive, referred to in the MD Regulations, state:

Devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in users' technique and environment. The information and instructions provided by the manufacturer should be easily understood and applied by the user.

Devices for self-testing must be designed and manufactured in such a way as to:

- ensure that the device is easy to use by the intended lay user at all stages of the procedure, and

¹⁸ IVD Directive, Art 3 and Annex I; MD Regulations, Reg 34(1)

¹⁹ Notified bodies are independent certification organisations which assess conformity of a device. They are appointed by the competent authority. Their activities include, quality assurance, examination of the design of a device and product verification. Where appropriate, and where a device conforms with the necessary standards of the IVD Directive, the notifying body issues a certificate which allows a manufacturer to apply the CE mark and distribute the device.

²⁰ IVD Directive, Art 4(1)

- reduce as far as practicable the risk of user error in the handling of the device and in the interpretation of the results.

Devices for self-testing must, where reasonably possible, include user control, i.e. a procedure by which the user can verify that, at the time of use, the product will perform as intended.²¹

- 4.9 There are also specific requirements relating to the information supplied by the manufacturer with self testing kits.²² For example, a clear description of what the test result will mean to the patient should be provided, as well as an explanation of the concept of a false negative/ false positive that can be understood by a non-professional. It is likely that if new legislation is introduced relating to HIV self testing kits, the regulations will have specific requirements on the information to be provided to patients and how this should be communicated.
- 4.10 Certain devices are considered high risk devices and require the greatest scrutiny before being placed on the market. The IVD Directive lists certain devices for which specific additional criteria should be met. In particular, Annex II, List A of the IVD Directive includes:

Reagents, and reagent products, including related calibrators and control materials, for the detection, confirmation and qualification in human specimens of markers of HIV infection.

- 4.11 For such devices, the European Commission has established a set of “Common Technical Specifications”. Under the IVD Directive, Member States can presume compliance with the essential requirements where the device is designed and manufactured in conformity with the relevant Common Technical Specifications.²³ The Common Technical Specifications which set out criteria for HIV testing kits were published in the Official Journal on 3 February 2009.²⁴ These specifications in effect set out common standards that should be met for particular high risk devices, and establish appropriate performance evaluation and re-evaluation criteria, batch release criteria, reference methods and reference materials. For instance, HIV testing kits must have a specificity of at least 99.5%.²⁵ As a general rule, manufacturers are required to comply with the Common Technical Specifications, and if for duly justified reasons they do not comply with them, they must meet standards that are at least equivalent to them.

Conformity assessment

- 4.12 In order to demonstrate compliance with the “essential requirements” of the Directive, the manufacturer must follow the conformity assessment procedure appropriate for the category of IVD concerned.²⁶ The conformity assessment route that a manufacturer must follow is determined according to the risk classification of the IVD, and as the risk classification increases, so does the level of detail and scrutiny of the examination by the notified body.
- 4.13 HIV testing kits are listed in Annex II, List A of the IVD Directive and are considered the highest risk devices, and therefore require the highest level of conformity assessment. A device listed in Annex II, List A of the IVD Directive can only be placed on the market if the manufacturer undertakes a quality assurance assessment, and an analysis of the device itself, overseen by the notified body (the actual procedures are complicated, and require compliance with various international standards to demonstrate that the essential requirements have been met, and that the manufacturing, quality and safety systems are acceptable).²⁷ In addition, higher risk category devices are expected to have been the subject of a clinical trial (known as a clinical investigation).
- 4.14 If appropriate, UK notified bodies may grant a certificate of compliance for a period of up to five years, which can be extended for a further five years on the manufacturer’s application.²⁸ The declaration of conformity, the technical documentation and the decision, reports and certificates of notified bodies must be kept available for inspection for a period of five years after manufacture of the last device.²⁹
- 4.15 Once the manufacturer is in compliance, and has a certificate of compliance from a notified body, he may

²¹ IVD Directive, Annex I, para.7

²² IVD Directive, Annex I, para. 8.7(t).

²³ IVD Directive, Art 5(3)

²⁴ Commission Decision of 3 February 2009 amending Decision 2002/364/EC on common technical specifications for in vitro-diagnostic medical devices, 2009/108/EC

²⁵ Commission Decision 2009/108/EC, paragraph 3.1.12

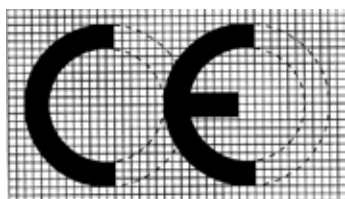
²⁶ IVD Directive, Art. 9, MD Regulations, Reg. 40, which cross-refers to the relevant Annexes in the IVD Directive

²⁷ MD Directive, Reg 40(3); IVD Directive, Art 9(2)

²⁸ MD Regulation, Reg 42(2) and (3); IVD Directive, Art. 9(10)

²⁹ IVD Directive, Art 9(7); MD Regulations, Reg 44(1)(g)

apply a CE mark to the IVDs he places on the market. The mark, as shown below, must appear in a visible, legible and indelible form on the device, where practicable and appropriate, as well as on the instructions for use and sales packaging. The CE mark must be accompanied by the number of the relevant notified body.³⁰



- 4.16 Once the CE mark is applied, certain devices must be registered with the national competent authority (in the UK, this is the Medicines and Healthcare products Regulatory Agency - MHRA³¹). A manufacturer must inform the competent authority when it first applies a CE marking to an IVD - this is a self-declaration process.
- 4.17 The concept of placing an IVD on the market refers to each individual device, not just the type of device. Therefore, each individual IVD must be made to the approved specifications of the IVD.³² Furthermore, if the design of a device is changed, the notified body must approve that change before the CE mark can be applied and before that newly designed IVD can be placed on the market.³³

5. What are the human rights issues surrounding HIVST?

- 5.1 There are three principal sources of human rights law in Europe: the European Convention of Human Rights, the European Social Charter, and the Charter of Fundamental Rights of the European Union.
- 5.2 The European Convention of Human Rights ("ECHR") is the most established source. It came into force in September 1953 and has its own dedicated court, the European Court of Human Rights ("ECtHR"). The ECHR was drafted by the Council of Europe - an organization set up as a group of like-minded nations, who pledged to defend human rights, parliamentary democracy, the rule of law and to make sure that none of the cruelties that emerged as a result of the world wars were repeated.
- 5.3 The ECHR is made up of a series of short Articles, which are short statements defining a right or freedom together with any permitted exceptions. The rights in the ECHR apply to everyone in the signatory countries. If a person believes that their Convention rights have been violated, they must first take action in their domestic courts. If they do not believe that the national court has adequately addressed a human rights issue, they may take their case to the ECtHR which is based in Strasbourg, France.
- 5.4 England and Wales passed its own Human Rights Act in 1998 ("HRA 1998"), which made the ECHR enforceable in UK courts. It came into force in October 2000. Until this point, UK citizens had to take their human rights claims directly to Strasbourg. Below, we will comment on the human rights issues from both a pan-European and a UK-specific perspective.
- 5.5 The European Social Charter ("ESC") is a treaty established by the Council of Europe. It is not enforceable in national courts although compliance is monitored by the European Committee of Social Rights which carries out annual surveys on all the members. In addition, certain organisations are entitled to submit complaints to the Committee against signatory states for breach of the ESC. The ESC contains specific provisions relating to health and the removal, as far as possible, of the causes of ill-health³⁴. It states that anyone without adequate resources has the right to social and medical assistance. We have not identified relevant complaints for the purposes of this research.
- 5.6 The Charter of Fundamental Rights³⁵ of the European Union ("the EU Charter") was implemented into EU law to recognise formally the rights and freedoms of every individual in the EU³⁶. It should be noted that the UK opted out of the Charter³⁷. The EU Charter mirrors the ECHR in many respects such as the right to a private life³⁸ but the scope of the EU Charter is wider. For instance, Article 35 recognises that everyone has the right of access to preventive healthcare and the right to benefit from medical treatment under conditions established by national laws and practices. Unlike the ECHR, the EU Charter is only applicable

³⁰ MD Regulations, Reg. 36 and IVD Directive, Art. 16(2)

³¹ The MHRA an executive agency of the Department of Health, is the competent authority responsible for monitoring the safety and efficacy of products in the UK.

³² IVD Directive, Art. 16(1)

³³ MD Regulations, Reg. 44(1) and IVD Directive, Annex IV, point 4.5

³⁴ European Social Charter (revised), 3 May 1996, art. 11 and 13.

³⁵ 2010/C 83/02

³⁶ Treaty on the European Union, Article 6

³⁷ Treaty of the Function of the European Union, Protocol 30

³⁸ Article 7

to Member States when they implement specific EU law³⁹. With respect to privacy issues, the Articles of the EU Charter⁴⁰ do not appear to extend the scope of existing EU data privacy rules. As we understand the position, there is no specific EU law dealing with access to healthcare or the protection of those infected with HIV; therefore, this Charter is not applicable in this context. Nevertheless, we note that the Court of Justice of the European Union (“CJEU”) is currently considering a case concerning Article 35 in the context of a number of issues discussed below⁴¹. The reference was filed relatively recently and we do not know when the judgment is due.

5.7 We have not identified any case law concerning the EU Charter that is relevant to the matters here under consideration. In any event, due to the EU Charter’s relatively recent introduction, the CJEU will often refer to ECHR case law when addressing questions concerning human rights⁴². We will, therefore, focus our analysis on the relevant Articles from the ECHR.

5.8 The rights protected by the ECHR overlap and in many instances more than one Article will be the subject of a claim. An abuse of human rights may be justified if it is in the public interest, so the courts often have to balance public considerations against individual rights when assessing claims. The Articles which are obviously engaged by the issues described below are: Article 8, the right to a private life, and Article 14, the prohibition of discrimination. There is no right to be tested for HIV or any other disease under the ECHR. In terms of Article 8, the ECtHR is sensitive to the stigma associated with HIV and is particularly protective of the privacy of an individual’s HIV status. This means that disclosures of a person’s HIV status or forcing someone to take an HIV test without their consent will, in most cases, be a violation of Article 8 of the ECHR. Discrimination against a person with HIV is not expressly prohibited by the ECHR, but there are examples of discrimination based on HIV status which were found to be in breach of Article 14.

5.9 Does every person have a right to be tested?

5.9.1 Neither the ECHR nor the HRA 1998 stipulates that individuals have a right to be tested for HIV nor is there a right to healthcare generally⁴³. Human Rights claims concerning access to healthcare tend to allege breaches of one or more of the following ECHR Articles: Article 2, the right to life; Article 3, the prohibition of torture; and, Article 8, the right to respect for private and family life. Errors of medical judgment or negligent administration of medical treatment are insufficient in of themselves for the responsible State to be found in violation of its human rights obligations⁴⁴.

5.9.2 Article 2 of the ECHR obliges States to refrain from unlawfully taking the lives of individuals and also imposes a positive obligation on States to take appropriate steps to protect the lives of those within its jurisdiction. The State has a duty to put in place an appropriate legal framework to protect people’s lives under Article 2. This obligation can extend to healthcare⁴⁵. Where such a framework is in place, the State will not be in breach of the right to life⁴⁶. The court gives States a margin of appreciation in respect of the provision of healthcare⁴⁷ and the provision of adequate healthcare does not necessarily entail offering unfettered access to all services and treatments.

5.9.3 There is no explicit right to HIV testing under English law. The Secretary of State for Health is obliged to ‘promote’ a comprehensive health service to the public free of charge⁴⁸. This has been translated by the NHS Constitution into a “right to receive NHS services free of charge”⁴⁹. The Secretary of State and other health authorities have a duty to take the NHS Constitution into account in exercising their obligations.⁵⁰ If HIV testing is a service available on the NHS, members of the public should be able to access the service. A decision to refuse access to NHS services must not be unreasonable.⁵¹

5.9.4 Most cases regarding access to medical treatment in the English courts stem from the fact that the resources available for the provision of healthcare are limited. While recognising the

39 Article 51

40 Articles 7 & 8

41 Case C-459/13, *Milica Široká v Úrad verejného zdravotníctva Slovenskej republiky*

42 See for example: Case C-131/12, paras 112 - 119, *Google Spain SL, Google Inc. v Agencia Española de Protección de Datos (AEPD) Mario Costeja González*

43 R. R. V. Poland, no. 27617/04 (26/5/2011) ECHR “...the Convention does not guarantee as such a right to free medical care or to specific medical services...” para 198

44 *Powell v. the United Kingdom* (dec.), no. 45305/99 (4/5/2000) ECHR

45 *Powell v. the United Kingdom* (dec.), no. 45305/99 (4/5/2000) ECHR

46 *Hristozov and Others v. Bulgaria* no. 47039/11 and 358/12 (13/11/2012) ECHR

47 The court has observed, and presumably been guided by, the fact that provision of healthcare in the EU remains the competence of Member States.

48 Article 1(1)

49 page 6 of The NHS Constitution for England, 26 March 2013, see also The Handbook to the NHS Constitution for England, 26 March 2013

50 Articles 1B(1) of the NHS Act 2006 and Article 2 of the Health Act 2009 place duties on the Secretary of State and various health authorities to ‘have regard to’ the NHS Constitution. Articles 13C and 14P of the NHS Act 2006 place a duty on certain health authorities to ensure health services are provided in such a way as to promote the NHS Constitution.

51 page 6 of The NHS Constitution for England, 26 March 2013, see also page 20 of The Handbook to the NHS Constitution for England, 26 March 2013

application of Article 2 in these circumstances, the English courts have generally refrained from interfering with the health authorities' discretion in respect of funding treatments⁵². The courts have nonetheless mandated that such decisions must take all relevant considerations and specific personal circumstances into account and not simply be based on a lack of resources⁵³. The courts have, in one case, concluded that considerations affecting the patient's Article 8 right to private and family life do not necessarily have to be taken into account. When deciding whether or not to exclude Article 8 factors from a decision pertaining to the provision of healthcare services, the healthcare authority in question must balance the interests of the individual seeking treatment with the interests of the community in maintaining a financially viable healthcare system.⁵⁴

- 5.9.5 With respect to breaches of Article 3 of the ECHR, violations occur when the individual has suffered torture and inhuman or degrading treatment of a minimum level of severity. In considering what constitutes 'degrading' "...the Court will have regard to whether its [the treatment of the individual] *object was to humiliate and debase the person concerned and whether, as far as the consequences are concerned, it adversely affected his or her personality in a manner incompatible with Article 3 (see, among other authorities, Wainwright v. the United Kingdom, no. 12350/04, § 41, ECHR 2006X)*."⁵⁵ It seems that, in the context of healthcare, once a legal framework is in place the State must not structure it so as to limit the real possibilities of accessing applicable services⁵⁶. The duty imposed by Article 3 will be breached when "*persons in a vulnerable situation who have, as a result of the callous indifference of healthcare professionals, been denied access to otherwise available diagnostic services to which they were entitled as a matter of law*".⁵⁷ Prisoners who were denied treatment for HIV, including testing, have successfully alleged that this constituted a breach of Article 3.⁵⁸ It is not entirely clear (but is unlikely) that the court would reach a similar conclusion if HIV testing was unavailable to the public generally.
- 5.9.6 Article 3 has also been invoked by HIV positive immigrants who were being deported to their home countries where adequate treatment was either unavailable or inaccessible. They alleged that the decision to expel them would inevitably result in their premature death from AIDS and this was tantamount to a violation of Article 3. The ECtHR found in favour of the appellant in *D v United Kingdom*⁵⁹, but emphasised the exceptional circumstances of this case and the compelling humanitarian considerations (the claimant was in the final stages of AIDS and had no prospect of medical care or family support at home). Relevant considerations include: the claimant's state of health at the time of the decision to remove or expel him; whether treatment is available in the home country albeit at considerable cost; prospects of family support and care upon return⁶⁰. It could be argued that an individual who is suffering greatly may have a right to be tested with a view to being treated.
- 5.9.7 In summary, an assessment as to whether denial of healthcare and, specifically, denial of HIV testing will breach a individual's human rights will largely depend on the circumstances of the case at hand. Additionally, if the individual has been denied healthcare on a discriminatory basis then there may be a breach of Article 2 (right to life) and Article 14, (prohibition of discrimination).

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

- 5.10.1 Article 8 of the ECHR grants people the right to respect for private and family life. This right can be curtailed to the extent that it is necessary in a democratic society and pursues a recognized legitimate aim (for instance the protection of health or morals). Any interference with a person's Article 8 rights must not only be reasonable, but also necessary; furthermore, any interference should not do more than is needed to meet the legitimate aim.
- 5.10.2 The concept of a "private life" is broad. Any interference with a person's body or the way the person lives their life is likely to affect their right to respect for their private life under Article 8. More particularly, Article 8 places limits on the extent to which a public authority can do things which invade a person's privacy in relation to their body without their permission.
- 5.10.3 The qualification that is most likely to apply in the context of an HIV diagnosis is the protection of

52 *R v Cambridge District Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898, CA

53 *R v North West Lancashire Health Authority, ex p A, D & G*. [2000] 1 WLR 977, CA. And *R v Swindon NHS Primary Care Trust* [2006] EWCA Civ 392

54 *R. (on the application of Condliff) v North Staffordshire Primary Care Trust* [2011] EWHC 872 (Admin)

55 *Hristozov and Others v. Bulgaria* no. 47039/11 and 358/12 (13/11/2012) ECHR para 110

56 *R. V. Poland* no. 27617/04 (26/5/2011) ECHR

57 *Hristozov and Others v. Bulgaria* no. 47039/11 and 358/12 (13/11/2012) ECHR para 112 see also *R.R. v. Poland, no. 27617/04, §§ 148-62, 26 May 2011*

58 *Logvinenko v Ukraine* no. 13448/07 (14/10/2010) ECHR

59 *No. 30240/96 (2/5/1997) ECHR*

60 *N v United Kingdom* no. 26565/05 (2008) ECHR

public health. However, the ECtHR has stated that the confidentiality of information concerning HIV infection requires special protection⁶¹.

- 5.10.4 There are few cases where protection of health was alleged as the justification for making someone disclose health records against their will. Disclosure will be justified if there is a pressing social need to disclose the medical information and the associated inquiry or investigation is conducted in a proportionate manner. For instance, the individual in question should be informed and given an opportunity to object unless there is a legitimate reason to proceed otherwise. In other words, the State must balance the individual's rights under Article 8 with the aim of protecting public health because disclosure can have devastating effects on the lives of those concerned.⁶²
- 5.10.5 Disclosures seem to be more common in the context of preventing disorder or crime. Individuals, including doctors, may be compelled to disclose information in the context of a criminal investigation or court proceedings. No violation was found when the medical records of the wife of an HIV positive man were disclosed to the court in the course of his criminal hearing. The disclosure had been justified in accordance with the qualifications of Article 8⁶³, however, publication of the wife's identity in the judgment was considered disproportionate and a violation was found. Similar findings have been made in other cases where publication of the identity of the HIV positive individual was not justified by any pressing need.⁶⁴
- 5.10.6 Doctors have a duty of confidentiality towards their patients (discussed below at paragraphs 7.4.6 and 7.4.7) but an overriding duty of disclosure may exist if a third party is at risk of harm. The overriding duty will arise where the doctor's knowledge of the risk to the third party was sufficient to make the disclosure 'just and reasonable'. The doctor must not ignore the risk created by the patient. He must balance his duty of confidentiality against his duties to society and other patients and act reasonably in the circumstances. If he does not act reasonably he could incur civil liability or risk professional sanctions.
- 5.10.7 In certain circumstances prescribed by law doctors may disclose confidential information to other authorities such as social services and schools. However, Article 2 of the ECHR (the right to life) can sometimes be violated when there is an obligation to provide personal data to the authorities, for instance by way of a census⁶⁵.

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

- 5.11.1 As stated above, Article 8 of the ECHR places limits on the extent to which a public authority can do things which invade a person's privacy in relation to their body without their permission. This includes activities such as taking blood samples and performing body searches. In short, an adult cannot be compelled to take an HIV test in England and Wales if they do not want to.
- 5.11.2 Article 8 has also been interpreted so as to give parents various important rights, including to make their own decisions regarding their children's medical treatment. However, in limited circumstances, parents can be compelled to have their children tested for HIV, even if the test is against the will of the parents.
- 5.11.3 In England and Wales there is a presumption that the parental views regarding the best interests of the child are to be respected. However, this presumption is capable of rebuttal. The Children Act 1989 states that the best interests of the child should be the paramount consideration in any court decision concerning the upbringing of a child and the Children Act imposes specific duties on local authorities⁶⁶ to protect children.⁶⁷ If a child is likely to suffer significant harm if they are not tested for a disease, the local authority may apply to court for an Emergency Protection Order⁶⁸ If the court grants such an Order, the local authority obtains shared parental responsibility of the child and may make arrangements for - and give consent to - testing and treatment.
- 5.11.4 To date, there has only been one published case concerning whether a parent can be compelled to have their child tested, C (A Child) (HIV Testing) [2000] W.L.R. 270. Here, a mother infected with HIV fell pregnant and, contrary to medical advice, decided to breastfeed her child without taking any medication prior to birth. The parents also refused to have their child tested for HIV. As a result, the local authority applied to court for an order that an HIV test should be performed on the

61 C.C. v Spain no. 1425/06 (6.10.2009) ECHR

62 Avilkina and Others v. Russia no. 1585/09 (6/6/2013) ECHR

63 Z. v. Finland no. 22009/93 (25.02.1997) ECHR

64 C.C. v Spain no. 1425/06 (6.10.2009) ECHR

65 X v UK, Application no. 9702/82, 30 DR 239

66 A local authority is an administrative body in local government

67 See- for example- section 17, which imposes a general duty on local authorities to safeguard and promote the welfare of the children within their area who are in need

68 Children Act 1989, section 44

child. Both of the parents were adamant that such a test should not be performed. On hearing the facts of the case, the court granted the application and ordered the test to be performed.

- 5.11.5 To succeed in its application, the local authority was required to provide clear evidence that was capable of persuading the court that the parents were not acting in the best interests of the child. The court believed that performing the test was in the best interest of the child on the basis that a positive result could lead to the provision of sound medical advice and a negative result would lead to further efforts to convince the mother to reconsider her decision to breast feed.
- 5.11.6 In 2009, the Children's HIV Association produced a set of guidelines regarding the testing of children with parents who are confirmed or suspected HIV-positive. These guidelines recommend that, before taking action in the courts, there should be a 6-12 month timescale of negotiation with parents about whether or not they should have their child tested. This timescale will vary depending on the age and health of the child. For instance, where young infants are concerned, the timescale is more urgent, as the risk of disease progression in the first year of life is high.
- 5.11.7 A child under the age of 16 may be able to consent to medical tests (see section 7.2 below). However, where a child is not deemed competent to give their consent, it is sufficient for one parent or carer with parental responsibility to consent to the test.

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

- 5.12.1 Article 14 of the ECHR contains a prohibition against discrimination where there is no objective or reasonable justification for treating that person differently. The Article is worded as follows:

The enjoyment of the rights and freedoms set forth in this convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.

- 5.12.2 Article 14 is not a free-standing right. For there to be a breach of Article 14, a complainant must first demonstrate that they are suffering discrimination related to an issue that falls within the scope of another convention article. This said, the complainant does *not* need to prove that this other Convention Article has been breached. Essentially, to prove a breach of Article 14, the complainant must show that they have been treated differently to someone in an analogous situation, simply because of their "status" (in this case, a diagnosis with HIV).
- 5.12.3 Discrimination against a person with HIV is not expressly prohibited by the ECHR, however, the use of the phrase "other status" in Article 14 creates an open-ended list of areas of unjust discrimination. In fact, a recent case in the ECtHR has found a breach of Article 14 (and Article 8) of the ECHR based on a person's diagnosis with HIV.⁶⁹ Here, an employee of a company (Complainant) told several other employees about his positive HIV status. This led to several employees calling for the Complainant's resignation. After several attempts to alleviate concerns (including an attempt to transfer the Complainant to a new department), the employer asked the Complainant to leave the company.
- 5.12.4 The Greek Court of Cassation held that the dismissal was fair and reasonable, given the "contagious" nature of HIV. The Complainant took his case to the ECtHR, relying on a breach of Article 14 (discrimination) in conjunction with Article 8 (right to private life).
- 5.12.5 As stated at paragraph 5.10.1, a signatory state to the ECHR (in this case Greece) may only interfere with a person's Article 8 rights to the extent that it is reasonable and necessary to do so in pursuit of a legitimate aim (such as the protection of public health). The ECtHR said that there was no risk of infection and the reaction of the Complainant's colleagues was not scientifically justified. Even if this was a popular prejudice and misconception, that cannot serve as adequate grounds for discriminatory treatment. Furthermore, it was not a mitigating factor that the Complainant would have created a hostile work environment if he had remained at the company. As such, the Greek court had not struck the appropriate balance of interests between the company and the Complainant so the ECtHR found a breach of Articles 8 and 14.
- 5.12.6 Furthermore, in the case of *Kiyutin v Russia*⁷⁰, the ECtHR held that, when assessing discrimination, a state has a narrow remit in assessing what is objective and reasonable when limiting a person's Article 8 rights, if a restriction is applied to a vulnerable group that has suffered considerable discrimination in the past. The court also held that people living with HIV were such a vulnerable group who have suffered a history of prejudice and stigmatisation (see *Kiyutin* ¶¶63-64).
- 5.12.7 Mr Kiyutin moved to Russia with his mother and half-brother, and had subsequently married a Russian national, with whom he had a daughter. The Russian authorities refused him a residence

69 I.B. c Greece, no. 552/10, (3 October 2013)

70 *Kiyutin v Russia* no. 2700/10 (10/3/2011) 53 E.H.R.R. 26

permit after he tested positive for HIV and the Russian courts upheld this decision. Mr Kiyutin challenged this at the ECtHR, who found in his favour. The court said that the protection of public health was a legitimate aim, however, the Russian government did not adduce compelling and objective arguments to show that its refusal of a resident's permit to Mr Kiyutin was objectively and reasonably justified on account of his health status (see ¶172).

- 5.12.8 The UK has specific legislation on equality and prohibits discrimination based on a number of "protected characteristics". Much like the ECHR, the Equality Act 2010 ("the Equality Act") prohibits discrimination on the grounds of age, race, belief, sex, and disability. The Equality Act promotes equal opportunity in the workplace and in wider society by outlawing discrimination based on these protected characteristics. HIV infection is expressly listed as a disability; more particularly, it is listed as a progressive condition which can give rise to a substantial adverse impairment.⁷¹ Therefore, people who have been diagnosed with HIV are protected from discrimination in a number of areas, including employment and recruitment.
- 5.12.9 For instance, the Equality Act now prohibits potential employers from asking job applicants to complete health questionnaires prior to an offer of employment. This means that less scrupulous employers are not able to filter out applicants with a disability or long term health condition. Furthermore, those suffering from HIV are also protected from discrimination in the workplace in the fields of, *inter alia*, working hours, pay and benefits, career development and dismissal and redundancy.
- 5.12.10 Furthermore, an employee who has HIV is entitled to ask the employer to make reasonable adjustments to their working environment so that such an employee can carry out their job without disadvantage. HIV is treated as a "disability" for the purposes of the Equality Act. Examples of these reasonable adjustments include allowing a disabled employee to take periods of disability leave as well as modifying procedures for testing or assessment in the workplace. What is reasonable is determined on a case-by-case basis and the employer should consider how effective a change will be in avoiding discrimination, the practicality of that measure and the cost of that measure.
- 5.12.11 As more is understood about the HIV virus and its transmission, many of the restrictions placed by English law on those who are more at risk of contracting the disease (e.g. gay men) are being removed. For instance, until recently, there was a lifelong ban on blood donation for any man who had ever had oral or anal sex with another man.⁷² In 2011, the health ministers in England, Scotland and Wales adopted the recommendations of a safety advisory board so that the only men prohibited from donating blood were those who have had anal or oral sex with another man in the past 12 months, with or without a condom. As a result of the change, more men, who were previously excluded from donating blood, can now do so, although sexually active gay men are still unable to donate. This is due to the fact that the window period⁷³ is one year for Hepatitis B and a maximum of three months for HIV.
- 5.12.12 As discussed at paragraph 3.6 above, the Department of Health released a statement in August 2013 about how it proposed to modernise rules surrounding HIV status.⁷⁴ As of February 2014, doctors and healthcare workers with HIV who are undergoing treatment will be able to take part in certain medical procedures from which they were banned.⁷⁵

⁷¹ Equality Act 2010 Schedule 1 para.6

⁷² Department of Health press release, Lifetime blood donation ban lifted for men who have had sex with men, 8 September 2011 <https://www.gov.uk/government/news/lifetime-blood-donation-ban-lifted-for-men-who-have-had-sex-with-men>

⁷³ The time period in which a person is infected with a disease but in which sero-conversion may still not be detected in a test of a blood or saliva sample.

⁷⁴ Department of Health press release: Modernisation of HIV rules to better protect public

⁷⁵ Letter from The Chief Medical Officer, Professor Dame Sally C Davies, Department of Health, dated 16 January 2014 regarding 'the practice of exposure prone medical procedures by healthcare workers living with HIV and Hepatitis B' https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=101791 see also 'The Management of HIV infected Healthcare Workers who perform exposure prone procedures: updated guidance, January 2014', Public Health England http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317140704390

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 Product liability claims may be made under the Consumer Protection Act 1987 ("CPA"), in the tort of negligence, or as a breach of contract for defective products that cause damage. Both the laws of negligence and contract will apply where a product is sold. The law of negligence will also apply in circumstances where a product is distributed freely but a contract is unlikely to be created between the seller and consumer in these circumstances. The CPA will apply if the product is placed on the market in the course of a business with a view to profit. The exact meanings of these terms are unclear and determining whether or not the CPA applies will depend on the circumstances in which the product in question was placed on the market.

HIVSTs supplied free of charge

6.2 The common law tort of negligence (failure to act with reasonable care) may apply even where a defective product is distributed without charge. In order to establish negligence, it is necessary to prove that the Defendant owed a duty of care to the Claimant, that he breached that duty by failing to take reasonable care, and that the specific breach caused the damage complained of. Such claims are commonly brought against the manufacturer of a defective product, although they may also be brought against other persons in the supply chain, if it can be established that any person was at fault. Organisations who distribute HIV self-testing kits, along with manufacturers, will owe a duty of care to the individuals that they can foresee will use the testing kits. The duty extends to anyone who is likely to be endangered by the product if it is defective. Liability could, therefore, extend to individuals who become HIV infected as a consequence of decisions taken on the basis of inaccurate test results.

6.3 The Claimant has the burden of proving, on the balance of probabilities, that the Defendant's product caused or materially contributed to the Claimant's injuries. The traditional test of causation is the 'but-for test': the Claimant must prove that, but for the Defendant's negligence the Claimant would not have sustained the injury. For instance, a third party who would have engaged in unsafe sex regardless of the outcome of his/her partner's test results, could not prove causation.

6.4 In negligence, manufacturers and (as applicable) suppliers owe a duty to take reasonable care in the design, manufacture and handling of products and in ensuring the provision of adequate warnings and instructions for use with the products they manufacture and/or supply. In relation to product information, care should be taken in considering what languages should be used as well as whether written warnings and labelling will be adequate in areas where literacy rates are low. In these circumstances, the supplier would have to discharge its duty of care via other reasonable means to ensure individuals who use the self-testing kits do so safely. The duty is on-going so manufacturers owe a duty to warn of dangers first identified after the product was supplied as a result of new knowledge derived from research or experience in the market. There is no duty to warn of dangers that are obvious or a matter of common knowledge.

6.5 In negligence, damages are compensatory i.e. they are awarded to put the injured party into the position that person would have been in if the negligent act had not occurred. Damages can be recovered for death or personal injury (including mental injury). Pure economic losses which are not a consequence of physical injury are not generally recoverable in negligence. Moreover, only damages which are not too remote are recoverable. Damages for a false positive test result may be recoverable by the test user for psychiatric injury suffered as a result of the diagnosis. There is unlikely to be much, if any, loss flowing from a false negative unless the results lead to a delay in receiving treatment which is detrimental to the individual's health or the user infects a third party. Third parties could potentially claim the costs of treatment which they would not have otherwise incurred had they not been infected with HIV.

6.6 In the case of mental injury, the English courts only permit recovery for recognised psychiatric injuries. Mere anxiety or distress is not actionable and is not, on its own, sufficient to ground a claim for damages.

6.7 The Consumer Protection Act 1987 may apply in circumstances where products are distributed freely. See paragraphs 6.9 to 6.15 below for further information.

6.8 If a product is sold rather than supplied free of charge the consumer will also have the right to sue for breach of contract.

Consumer Product Act 1987

- 6.9 The CPA, which implements the EU Product Liability Directive, 85/374/EEC, in the UK, applies to products supplied during the course of a business. The Act imposes liability on the “producer” of defective products for damage caused by the defect. A product is defective if it is not as “safe as persons generally are entitled to expect”, taking account of a number of factors including any instructions or warnings provided with the product and the manner in which it has been marketed. Liability is strict: it is not necessary to prove that the producer was at fault in causing the defect. The Claimant need only prove a defect and a causal relationship between the defect and the injury. Therefore, claims are usually brought under the CPA as opposed to negligence because of its strict liability regime.
- 6.10 Liability is imposed on the ‘producer’ which is defined as the manufacturer, the first importer of the product into the EU, or an own brander (i.e. any person who, by labelling or the use of trademarks, holds himself out as being the producer of the product). The supplier (whether the retailer, distributor or a wholesaler) may be liable in place of the producer only if he fails to identify the producer or at least the person who supplied the product to him.
- 6.11 As with negligence, the Claimant has the burden of proving, on the balance of probabilities, that the Defendant’s product caused or materially contributed to the Claimant’s injuries. The traditional test of causation is the ‘but-for test’: the Claimant must prove that, but for the Defendant’s supply of a defective product, the Claimant would not have sustained the injury.
- 6.12 The CPA specifically identifies the “get up” of the product and any instructions or warnings relating to its use as part of all the circumstances to be taken into account in assessing if the product is defective. Whilst it seems clear that warnings provided directly to consumers with the product must be taken into account in assessing liability under the CPA, the extent to which warnings provided to intermediaries, such as doctors, should be taken into account as part of “all the circumstances” is uncertain and has not yet been decided by the English courts. In the so-called “Hepatitis C”⁷⁶ case, the court ruled that the medical profession’s knowledge of the possible risk of infection with the Hepatitis C virus arising from the use of blood products was irrelevant in assessing whether those products were defective. The defect was assessed by reference to the legitimate expectations of the public at large. The fact that physicians were aware of the risks of infection was irrelevant as they did not generally inform patients of those risks and the risks were, therefore, not known and accepted by patients. It remains uncertain how the English courts would approach this issue if there was evidence that the intermediary generally provided warnings to consumers. It should be noted that the Hepatitis C decision concerned a product which fell outside the statutory system for licensing of medicinal products and the regulatory requirement for appropriate prescribing information.
- 6.13 Under the CPA the following defences are available:
- the defect is due to compliance with legal obligations imposed by UK or EU law. This defence is narrow. It is not enough to show compliance with regulatory requirements. It may be relevant if a specific form of design of product or warning was mandated by the authorities and this design or warning was later judged to be defective/inadequate;
 - the defective product was not supplied by the Defendant;
 - the product was not supplied for profit and in the course of business;
 - the defect did not exist at the time the product was supplied;
 - the so-called “development risks defence” applies: the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the allegedly defective product might be expected to have discovered the defect if it had existed in his products while they were under his control; and
 - if the product was a component used in another product, the producer of the component will not be liable if he can show that the defect was due to the design of the final product, or to defective specifications provided to the component producer by the producer of the final product.
- 6.14 We understand that the HIV self-testing kits will be supplied for the benefit of the community. In these circumstances the defence excepting products supplied otherwise than in the course of the defendant’s business *and* otherwise than with ‘a view to profit’ may apply. This exception can cover products which are sold or supplied without charge. The term “*business*” includes a trade or profession but the term ‘*with a view to profit*’ is not defined. The individual circumstances of the activity which resulted in the product being placed on the market will need to be considered. Factors which courts are likely to take into account are the scale of the activity, whether the activity is the primary function of the charity, how the activity is organised, whether the activity results in revenue and how the revenue is used. In the charitable context non-fundraising activities could arguably be exempt from the CPA.
- 6.15 Under the CPA, damage includes death or personal injury (including mental injury) or loss of, or damage to, property for private use and consumption (provided the damages recoverable in respect of property loss

exceed the minimum threshold of £275). Damages are not recoverable in respect of damage to the defective product itself.

Is the answer different if a kit is sold rather than supplied free of charge?

- 6.16 As explained above, all three liability regimes may apply when a product is sold. We discuss the application of contract law in the following paragraphs. The sale and purchase of an item creates a contract between the seller and the purchaser and defects in the product may be actionable as a breach of contract.
- 6.17 Claims for breach of contract may only be brought by the consumer against the immediate supplier of the defective product. Third parties cannot normally claim for damages under English contract law (unless specified in the contract). Under the Sale of Goods Act 1979 (as amended) and the Supply of Goods and Services Act 1982, standard terms are implied into all contracts for the sale of goods, unless the parties agree to exclude them. Products sold in the course of business must:
- be of satisfactory quality, including fit for purpose; and
 - comply with the description applied to them or a sample supplied.
- 6.18 Public statements made by manufacturers, importers, distributors and retailers of the product, for example, in advertising, must also be factually correct and may form part of the retailer's contract with the consumer or give rise to a separate claim for damages based on misrepresentation. The seller will not be liable for faults drawn to the buyer's attention prior to the contract, or which should have been revealed by the buyer's examination of the goods.
- 6.19 There are also restrictions on the extent to which manufacturers, retailers and others in the supply chain can exclude or limit their liability. Under the Unfair Contract Terms Act 1977, the implied term of satisfactory quality cannot be excluded in consumer contracts (and it may only be excluded in business contracts if the exclusion is reasonable in the circumstances). Liability under the CPA and for death or personal injury resulting from negligence can never be excluded. Other liability for negligence may only be excluded if the restriction is reasonable. Additional rights apply in respect of standard terms not individually negotiated with consumers.
- 6.20 Contractual liability may be passed down the supply chain through the series of contractual agreements between the manufacturer, distributor, retail supplier, customer and others, depending on proof of breach of the contractual terms in each case and subject to any valid exclusion clauses.
- 6.21 In contract, damages are intended to put the injured party into the position he would have been in if the contract was properly performed. Damages are usually awarded for monetary loss (for example, in respect of damage to property and to the defective product itself), but they can include non-pecuniary losses, such as damages for death or personal injury (including mental injury), where this was within the parties' contemplation as not unlikely to arise from the breach of contract. Economic losses, such as loss of profits, are recoverable if these are a foreseeable consequence of the breach.

7. Further issues concerning HIV regarding consent, counselling, disclosure and confidentiality

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

- 7.1.1 The Department of Health's Reference guide to consent for examination or treatment⁷⁷ states that it is a general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation of a person. Consent will only be valid if it has been given voluntarily by someone who has capacity to consent and who was appropriately informed in advance of the nature and purpose of the testing. In most cases the person providing consent will be the patient or the parent of a patient who is under 18 years of age. Written consent is not required except in a few circumstances prescribed by law. Consent can be implied, for instance, if an individual extends their arm to allow a healthcare practitioner to take their blood pressure. Nevertheless, it is considered good practice to obtain written consent especially for significant procedures. Any consent, whether written, oral, or implied will be invalidated if the patient does not have capacity, has not consented voluntarily, or was not provided with appropriate information about the intervention.
- 7.1.2 If testing proceeds without consent liability may arise under the tort of trespass to the person. This tort protects the individual's right to self-determination over his/her body. It is actionable regardless of whether the trespass causes physical harm so even interference such as touching can be considered a trespass to the person if the action was deliberate and in excess of the level of contact expected in everyday life. The fact that the patient consented will not be a viable defence in a trespass claim if the patient can show that he was not properly informed as to the nature of the procedure. If the patient was misinformed only about the risks/benefits of the procedure he/she will not have a claim in trespass. However, the patient may have a claim in negligence, if an injury

⁷⁷ 2nd ed., July 2009 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf)

was sustained and a cogent case can be made that it would have been avoided or minimised had appointed information been provided.

- 7.1.3 If the patient refuses consent their wishes must be respected. However an exception exists in Part 2A of the Health Protection (Notification) Regulations 2010/659. This statutory instrument allows local authorities to apply to the courts for an order imposing certain restrictions or requirements on a person who presents, or could present a significant harm to human health. If granted, the subject can be required to undergo medical examination (but not treatment), be detained or kept in quarantine, provide information or answer questions about their health or other circumstances, and have their health monitored, amongst other requirements. With respect to individuals infected with HIV, the Department of Health's guidance⁷⁸ states:

"It is not uncommon for sexual health services to provide care for people who present repeatedly with STIs, some of whom may also have a long-term infection such as HIV or hepatitis C. It is not intended for Part 2A Orders to be routinely used in relation to people who continue to engage in unsafe sex, posing a risk to their partners. Longer-term and consensual interventions remain the usual and preferred approach for long-term conditions such as HIV or hepatitis B or C infection."

- 7.1.4 The Guidance goes on to state that an application for a Part 2A Order in relation to a person with an STI should be balanced against the wider implications for public health, for instance, the possible loss of trust by relevant communities in the local clinic's confidentiality policies.
- 7.1.5 The ECtHR ruled on a case where an HIV positive man had been subjected to restrictions on movement contained in Sweden's Infectious Diseases Act 1988 after unknowingly transferring the virus to another individual. He failed to attend some mandatory medical appointments and was compulsorily detained in isolation for a total of 18 months over the course of six years. The Court found that the appellant's right to liberty under Article 5 had been breached. Compulsory isolation should only be used as a last resort and in this case the measures taken proved to be disproportionate to the risk he posed to the public.⁷⁹

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 England, children are defined as those under 18 years of age. Once a person reaches their 18th birthday, they are assumed to be a competent adult capable of consenting or refusing treatment, unless other factors prevent them from making informed decisions.⁸⁰ Nevertheless, a young person may make decisions about their medical treatment - in the same way as if they were an adult - if they are deemed to have capacity to make these decisions.
- 7.2.2 First, those aged 16 and over are presumed to have the capacity to consent to medical treatment.⁸¹ However, this is a rebuttable presumption and the court may (and has) interfered where it is necessary and reasonable to do so. For instance, a girl of 16 refused treatment for anorexia but was, in any event, treated for the condition. She applied to the court claiming that she was being treated without her consent. The court found that she was not competent to make a decision about whether treatment was in her best interests and, while due weight had to be attached to her wishes, the court held that it must order treatment pursuant to its inherent jurisdiction to protect minors under section 1 of the Children Act 1989.⁸²
- 7.2.3 Furthermore, children under the age of 16 may still give their consent to medical procedures if their capacity is assessed and they are deemed to have the maturity and intelligence to fully understand the nature of the treatment, the options, the risks involved and the benefits. This is known as being Gillick competent.⁸³
- 7.2.4 In Gillick, the court said that provided the patient, whether a boy or a girl, is capable of understanding what is proposed, and of expressing his or her own wishes, there was no good reason for holding that he or she lacks the capacity to express them validly and effectively and to authorise the medical man to make the examination or give the treatment which he advises.

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

- 7.3.1 The UK National Guidelines for HIV Testing suggest that arrangements for communicating results

⁷⁸ Department of Health, *Health Protection Legislation (England) Guidance 2010*, 25 March 2010

⁷⁹ *Enhorn v Sweden* no. 56529/00 (25/1/2005) ECHR

⁸⁰ Family Law Reform Act 1969, section 1

⁸¹ Family Law Reform Act 1969, section 8

⁸² See *Re J (a minor) (medical treatment)* [1992] 3 WLR 758

⁸³ The concept of "Gillick competence" emerged from the case of *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112.

should always be discussed and agreed with the patient at the time of testing, particularly where the test is being performed in an outpatient or emergency care setting. Furthermore, the guidelines strongly recommend the face-to-face provision of test results.⁸⁴

PRE-TEST DISCUSSIONS

7.3.2 The Royal College of Physicians (of London) guidance on testing for HIV also states that there should be pre-test discussions⁸⁵. The primary purpose of these discussions is to establish informed consent for testing and it is said that there is no need for lengthy discussion unless requested. Physicians are guided to focus on two points:

- The benefits of testing to the individual;
- Details of how the results will be given.

7.3.3 If a patient refuses a test, it is suggested that the reasons should be explored and documented to ensure that these are not due to incorrect beliefs about the virus and/or the consequences of testing. It is also important to establish that the patient understands what a positive and a negative result mean in terms of infection with HIV as some patients could wrongly interpret 'positive' as good news.⁸⁶

POST-TEST DISCUSSIONS

7.3.4 Arrangements for communicating the results should always be discussed and agreed with the patient at the time of testing. When it comes to the provision of results, face-to-face meetings are strongly recommended for:

- Patients more likely to have an HIV-positive result;
- Those with mental health issues;
- Those for whom English is a second language;
- Young people under 16 years; and
- Those who may be highly anxious or vulnerable.⁸⁷

7.3.5 If a person tests positive, that person should be given their result directly by the testing clinician and not via any third party, including relatives or other clinical teams, unless the patient has specifically agreed to this.⁸⁸ It is also considered best practice that, where an individual tests HIV positive, that person is seen by a specialist as soon as possible, ideally within 48 hours, and certainly within two weeks of receiving the result.⁸⁹

7.3.6 Following the provision of the results it is recommended that a nurse/doctor specialising in HIV has a more detailed discussion with the person so that the individual can better understand issues such as assessment of the stage of the disease, various treatment options and considerations, and partner notification.⁹⁰ The National Health Service (NHS) provides treatment and counseling for those persons who are HIV positive. NHS services are free of charge, except in limited circumstances sanctioned by Parliament.⁹¹ As far as we are aware, there are no circumstances sanctioned by Parliament that would prevent a person from receiving free counselling and treatment for HIV.

7.4 Confidentiality of test results

7.4.1 There are three principal sources of law which protect confidential health or other private information in the UK: the Data Protection Act 1998, Article 8 of the ECHR (discussed above at section 5.10), and the duty of confidence under common law which gives rise to the tort of breach of confidence where the duty is not respected. The Data Protection Act applies to organised data e.g. databases. The law of confidence applies to situations where private information is disclosed to another person on condition (either expressly or implied) of confidentiality e.g. during a consultation with a doctor. Article 8 of the ECHR protects individuals' private lives against interference from the State. In addition, the NHS (Venereal Diseases) Regulations 1974⁹² are designed to protect the

84 UK National Guidelines for HIV Testing 2008

85 Royal College of Physicians - Testing for HIV: Concise Guidance to Good Practice Series

86 UK National Guidelines for HIV Testing 2008 (page 10)

87 *ibid*, page 11

88 *ibid*, (page 4)

89 British HIV Association, Royal College of Physicians, British Association for Sexual Health and HIV, British Infection Society (2007) *Standards for HIV Clinical Care*

90 *ibid*

91 The NHS Constitution for England, 2013

92 SI 1974/29

privacy of patients with sexually transmitted diseases within the healthcare system. There is some overlap between these different provisions, in particular with Article 8. Although the Convention only applies to State practices, the courts are obliged to act in accordance with it so they will take into account Article 8 whenever they hear proceedings concerning privacy. Article 8 has already been discussed at section 5.10 above. The protection afforded by the Data Protection Act and the law of confidence are reviewed below along with the regulations applicable to the NHS.

- 7.4.2 The Data Protection Act 1998 (“the 1998 Act”) protects data concerning an identifiable individual, such as test results, which are held within a ‘relevant filing system’⁹³. The 1998 Act applies to the individuals and organisations which determine how the personal data is processed, ‘data controllers’. Processing of personal data is broadly defined and includes recording, altering, erasing, using, and disclosing data. Data processing must be carried out in conformity with the conditions and Principles⁹⁴ stipulated in the 1998 Act. With regards to confidentiality, the 1998 Act obliges data controllers to implement measures to prevent unlawful access to the data⁹⁵. In addition, controllers can only process data in accordance with a specified purpose⁹⁶ and the processing must be conducted fairly and lawfully⁹⁷. These obligations effectively prevent disclosure of personal data to third parties, unless the data subject has consented to this or the disclosure was necessary under the terms of one of the other conditions listed in Schedule 2 to the 1998 Act such as that the disclosure was required for medical purposes to facilitate necessary treatment⁹⁸. Special provisions apply to information categorised as “sensitive”.
- 7.4.3 Health data, such as blood tests, are considered sensitive data and processing of such data must also comply with at least one condition from Schedule 3 of the 1998 Act⁹⁹. The conditions most relevant in the context of health data will be the requirement to obtain express consent from the data subject, or justification on the basis that the disclosure was necessary for medical purposes, and was undertaken by a health professional or by someone who was subject to an equivalent duty of confidentiality. The guidance of the General Medical Council (“GMC”) on confidentiality states that express consent should be sought before disclosing identifiable information for purposes other than the provision of the patient’s care or a local clinic audit¹⁰⁰.
- 7.4.4 Data within the NHS concerning someone’s STI status is subject to additional confidentiality requirements. The NHS (Venereal Diseases) Regulations 1974¹⁰¹ provide that any information capable of identifying an individual who is examined or treated for any sexually transmitted disease, including HIV, shall not be disclosed, other than to a medical practitioner in connection with the treatment of the individual or for the prevention of the spread of the disease. The GMC’s note on the confidentiality of information about serious communicable diseases¹⁰² advises doctors that they should not inform anyone outside the healthcare team of the patient’s diagnosis without the patient’s consent. The Department of Health’s guidance on health protection states that “*Patient confidentiality is of vital importance in HIV and STI settings to retain patients’ trust in health services and to encourage access to clinics and services for information and advice, testing, diagnosis and treatment.*”¹⁰³.
- 7.4.5 The NHS (Venereal Diseases) Regulations 1974¹⁰⁴ make provision for tracing of sexual contacts, but also seeks to ensure that the identities of patients and contacts remain confidential. Once an HIV diagnosis has been established a healthcare professional will try - with the consent of the HIV positive person - to identify individuals who have had contact with that person and may be at risk of having contracted HIV and will invite them for testing. If consent to this process is refused the GMC advises that it is permissible to notify the party at risk on the basis that it is in the public interest, but the notifier must try to avoid disclosing the identity of the HIV positive person, unless

93 The UK Information Commissioner considers that “a relevant filing system exists where records relating to individuals (such as personnel records) are held in a sufficiently systematic, structured way as to allow ready access to specific information about those individuals.” From ICO *The Guide to Data Protection* p 20 para 5

94 The Principles are contained in Schedule 1 of the Act

95 Schedule 1, 7th Principle

96 Schedule 1 2nd Principle

97 Schedule 1, 1st Principle

98 Condition (4), Schedule 2 “*The processing is necessary in order to protect the vital interests of the data subject.*”

99 Processing must comply with at least one condition stipulated in Schedule 3

100 General Medical Council, *Confidentiality: disclosing information about serious communicable diseases*, September 2009, para 33

101 SI 1974/29

102 Paragraph 8, September 2009

103 Department of Health, *Health Protection Legislation (England) Guidance 2010*, 25 March 2010 p 18

104 SI 1974/29

this is impracticable¹⁰⁵.

- 7.4.6 There is no specific law of privacy under English common law. Instead, individuals rely on the law of confidence which applies in situations where a breach of confidence may cause damage. The law of confidence will always apply in a patient/doctor setting. In order to establish a breach of confidence the information in question must have been confidential in nature, it must have been imparted from one person to another “in circumstances importing an obligation of confidence”, and the information must have been disclosed to a third party in a way that is detrimental to the person to whom it relates. A breach of confidence can be justified if it is in the public interest, which is distinct from a situation where the information disclosed was merely interesting to the public. The nature of the information revealed is relevant when judging the balance between private and public interests and it is likely that disclosure of information as sensitive as someone’s HIV status would require very strong justification in order for it to be in the public interest.
- 7.4.7 In addition to the duty of confidence, doctors and healthcare practitioners are subject to the standards set by their applicable regulatory bodies, including standards in relation to confidentiality. When these standards are breached the member in question risks removal of their right to practice. For more information on the confidentiality of HIV patients’ information in the healthcare system please refer to the useful report produced by the National AIDS Trust, *Confidentiality in healthcare for people living with HIV*¹⁰⁶.

7.5 Duties of disclosure to partner/employer/insurer

PARTNER

- 7.5.1 There is no statutory duty to disclose the fact that one is HIV positive to a partner or spouse. An HIV positive individual will be entitled to keep this information confidential from his/her partner in accordance with her or his right to privacy, provided no contacts are initiated that could reasonably be expected to lead to transmission of HIV.
- 7.5.2 We have not identified any precedents but we consider that a duty of care between partners could arise under the common law of negligence if there is a risk of transmission from one partner to the other. In order for the tort of negligence to apply the HIV positive individual must owe his or her partner a duty of care. The term duty refers to a “*relationship by which an obligation is imposed upon one person for the benefit of another to take reasonable care in all the circumstances.*”. A duty of care will generally be imposed when the harm which occurs is foreseeable, there is a sufficiently proximate relationship between the individuals, and it is fair, just and reasonable in all the circumstances to impose a duty of care. Discharging this duty of care may or may not require disclosure of his or her HIV status, for instance, requiring the use of protection during sex may be sufficient.
- 7.5.3 In addition to civil liability, there is risk of criminal prosecution for transmitting HIV if a person does not inform their partner, yet makes a conscious decision to have unprotected sex with that partner. This is a serious conviction in England and Wales and can lead to a substantial jail sentence. This is discussed in more detail in section 8 below.

EMPLOYER

- 7.5.4 Employees are not obliged under English law to disclose their disability (HIV status) at any specific moment. Every employment contract contains various implied duties and obligations but these do not include a duty to disclose medical conditions.
- 7.5.5 As discussed in section 5.12 above, since the introduction of the UK Equality Act, prospective employers may only ask questions about a job applicant’s health and/or disabilities in limited circumstances (e.g. for specific jobs, such as for appointment as a nurse, doctor or dentist). Furthermore, after an offer of employment has been made, an employer can ask questions about the health of the applicant only to the extent that the information is relevant to the performance of the job that has been offered. For example, if the job requires extensive travel to a country with travel restrictions on people with HIV, it would be legal to ask about HIV status. The implied duties in contract include a duty of good faith and fidelity and, therefore, the employee would need to be honest towards the employer with regard to his or her medical status, to the extent that it affects the employee’s ability to perform their employment responsibilities. If a person lies to the employer about his or her HIV status (where it is relevant to the performance of the job) and the employer later finds out, this could potentially be grounds for dismissal for breach of mutual trust.
- 7.5.6 An employer cannot make any reasonable adjustments to the workplace until they become aware of the employee’s medical status and so - even if a person does not want to make a disclosure to work peers at large - it may be prudent for a person to disclose his or her HIV status if the person

¹⁰⁵ General Medical Council, *Confidentiality: disclosing information about serious communicable diseases*, September 2009

¹⁰⁶ Report: December 2009 <http://www.nat.org.uk/media/Files/Publications/Dec-2009-Confidentiality-in-healthcare-for-PLHIV.pdf>

is comfortable doing so. An employer would not be allowed to share this information with other employees, as the 1998 Act ensures that medical information, such as a person's HIV status, must be kept confidential.

- 7.5.7 Those working in the healthcare sector are obliged to inform their occupational health physician if HIV positive and to avoid performing invasive procedures. However, this changed in February 2014 (see paragraphs 3.6 and 5.12.12 above). While there is still a requirement to disclose an HIV positive diagnosis, medical practitioners no longer face an absolute bar from performing invasive surgery.¹⁰⁷

INSURERS

- 7.5.8 The Consumer Insurance (Disclosure and Representations) Act 2012 (the "2012 Act") places a duty on insurers to ask customers all relevant questions about the specific information required upon entering into the contract. Consumers in turn have a duty to take reasonable care not to make a misrepresentation during pre-contractual negotiations relating to a contract of insurance. The duty extends to insurance renewals. In determining the standard of reasonable care the courts will consider relevant explanatory information, and the clarity and specificity of the insurer's questions.
- 7.5.9 The insurer will not have a remedy against the consumer unless it can show that the consumer did not take reasonable care when making disclosures and representations to the insurer. An individual who is unknowingly HIV positive when he enters into an insurance contract should not have any claims denied on the basis that he did not disclose this information when he entered into the contract. However, an applicant who is aware that he or she has been exposed to the risk of HIV infection and did not take steps to confirm his or her HIV status may not be able to argue that he or she took reasonable care not to make a misrepresentation to the insurer. The extent that an individual can rely on the 2012 Act's protection will depend on the circumstances of each case.
- 7.5.10 If the consumer fails to take reasonable care and the misrepresentation induced the insurer to enter into the contract, the insurer will have a remedy. The type of remedy to which the insurer is entitled depends on whether the consumer's misrepresentation was deliberate/reckless i.e. the consumer knew the response was incorrect or acted without care or regard for the truth, or careless i.e. the consumer genuinely believed the statement was true, but did not take sufficient care to check the facts. If the misrepresentation was deliberate or reckless the insurer can act as though the contract never existed, refuse all claims and retain any premiums paid, unless it would be unfair to the consumer to retain them. In the case of a careless misrepresentation, the contract can be amended to include the terms on which the insurer would have entered into the contract had there been no misrepresentation. If the insurer would not have entered into the contract, in the face of a correct representation, it can refuse all claims, but must return the premiums paid.

¹⁰⁷ Letter from The Chief Medical Officer, Professor Dame Sally C Davies, Department of Health, dated 16 January 2014 regarding 'the practice of exposure prone medical procedures by healthcare workers living with HIV and Hepatitis B'

8. What are the criminal implications of transmitting - or being reckless as to transmission of - HIV?

8.1 Criminal proceedings can only be brought by certain public authorities which, for more serious crimes, is almost always the Crown Prosecution Service (CPS). There are three classifications of offence in England that determine which Court may hear a case as well as the maximum penalty.

8.2 There is no legislation that specifically criminalises HIV transmission and so the offences are prosecuted under the Offences against the Person Act 1861 ("the 1861 Act") for reckless, intentional or attempted intentional transmission of HIV. The offences relevant to HIV are:

- **Breach of section 20 of the 1861 Act**- this is an "either-way offence"¹⁰⁸ meaning it can be tried either before magistrates alone or in a higher court before a jury. It carries a maximum penalty of five years' imprisonment and/or an unlimited fine; and
- **Breach of section 18 of the 1861 Act**- this is an indictable only offence. This category of offence is reserved for the most serious criminal charges and is triable only by jury in the Crown Court. The most severe sentence, if found guilty, is life imprisonment.

8.3 A person facing criminal charges is innocent until proven guilty. The standard of proof in criminal cases is usually "beyond reasonable doubt", i.e. that no other logical explanation can be reached from the facts, except that the defendant committed the crime. It is established common law in England that "*an act does not make a man guilty of a crime unless his mind be also guilty*".¹⁰⁹ Therefore, in order to prove a crime, the CPS must, therefore, establish:

- *Actus reus* - that the defendant has committed all the elements of an offence (or sometimes omitted to do something) set out in the legislation;¹¹⁰ and
- *Mens rea* - that the defendant had the intention to commit the criminal act.¹¹¹

8.4 In certain defined cases, a person may commit a criminal offence even though he did not intend to commit one or more elements of that crime. These are called strict liability offences. However, *mens rea* (intent) is always a relevant element of a crime concerning the transmission of HIV and so we do not further address strict liability.

CRIMINALITY OF TRANSMITTING HIV

8.5 Until 2004, English courts consistently ruled that the transmission of a sexually transmissible infection could not constitute an offence of 'inflicting grievous bodily harm' under the 1861 Act. This was on the grounds that the term 'infliction' implies some sort of attack, rather than simply causing harm. This was overturned in the case of *R v Dica* [2004]¹¹², where it was recognised that person-to-person transmission of a sexual infection that will have serious, perhaps life-threatening, consequences for the infected person's health can amount to a criminal act.

8.6 The offences are more particularly defined and prosecuted according to the CPS documents 'Intentional or Reckless Sexual Transmission of Infection'¹¹³ and 'Policy for prosecuting cases involving the intentional or reckless sexual transmission of infection'.¹¹⁴ The policy documents state that there are three offences related to the transmission of HIV:

- "reckless transmission" (prosecuted under section 20);
- "intentional transmission" (prosecuted under section 18); and
- "attempted intentional transmission" (also prosecuted under section 18).

8.7 It is not a criminal offence to transmit HIV to a sexual partner if you were unaware you were HIV positive. As the CPS Guidance states, "*the criminality of [committing the offences] lies in the mens rea*".¹¹⁵ If a defendant was unaware of such HIV status at the time of intercourse, that person cannot have the *mens rea* (guilty mind) to commit an offence.

INTENTIONAL TRANSMISSION AND ATTEMPTED INTENTIONAL TRANSMISSION

¹⁰⁸ More serious "either-way" offences will be tried in the Crown Court. Less serious cases can be tried in a lower court called the Magistrates' Court which has a lower sentencing power of a maximum of six months' imprisonment and/or a fine not exceeding £5,000.

¹⁰⁹ *Haughton v Smith* [1973] 3 All E.R. 1109.

¹¹⁰ *R v Deller* [1952] 36 Cr App Rep 184, CCA

¹¹¹ Expressions indicating this mental element include: 'with intent'; 'recklessly'; 'maliciously'; 'wilfully'; 'knowingly'; 'knowing or believing'; 'fraudulently'; and 'dishonestly'

¹¹² *R v Dica* [2004] 2 Cr App. R. 28

¹¹³ Crown Prosecution Service Prosecution and Policy Guidance "Intentional or reckless sexual transmission of infection"

¹¹⁴ Crown Prosecution Service Guidance "Policy for prosecuting cases involving the intentional or reckless sexual transmission of infection"

¹¹⁵ Crown Prosecution Service Prosecution and Policy Guidance "Intentional or reckless sexual transmission of infection", page 2

- 8.8 To prove intentional transmission the prosecution must show that there is both scientific/medical evidence, as well as factual evidence that demonstrates the defendant deliberately intended to inflict grievous bodily harm on the complainant by transmitting HIV. The mere fact that the defendant concedes the existence of such an intention is not sufficient on its own for a guilty verdict; there must be further evidence to demonstrate that the defendant's account is compatible with the contention that the defendant intentionally infected the complainant.¹¹⁶
- 8.9 Unlike cases of reckless transmission, the consent of the complainant to sexual activity in the knowledge that the defendant is infectious is not a defence to a charge of intentional transmission according to English case law. This is based on the fact that the court does not consider it in the public interest that people should intentionally try to cause or should cause each other actual bodily harm for no good reason. As such, the act is unlawful regardless of consent.¹¹⁷
- 8.10 Where a person has failed to transmit HIV to another person, but the CPS believe that such a person they have deliberately intended to do so, the CPS may pursue a charge of attempting to commit the section 18 offence.¹¹⁸

RECKLESS TRANSMISSION

- 8.11 This charge will be utilised where a person actually transmits HIV to a complainant but without the direct intention to do so. To prove that a defendant has acted recklessly the CPS must prove that the defendant foresaw that the complainant might contract HIV via unprotected sexual activity but that the defendant still proceeded to take that risk.¹¹⁹ Factors that will affect whether a defendant is reckless will include the number of times the defendant exposed the complainant to the risk of infection and the nature and status of the infection (e.g. where the defendant had contracted a particularly virulent strain of HIV and knew this).¹²⁰
- 8.12 The National AIDS Trust, the Terrence Higgins Trust, and NAM Publications (an HIV and AIDS organisation) have produced a guidance note which sets out a simplified guide as to what the CPS must prove before a person can be found guilty of recklessly transmitting HIV.¹²¹ The five steps are:
- i) the defendant had HIV and knew this (or had received an HIV positive diagnosis);
 - ii) the defendant understood how HIV is transmitted;
 - iii) the defendant had sex with a sexual partner who was unaware of the defendant's HIV diagnosis;
 - iv) the defendant had sex without a condom (use of a condom throughout penetrative sex means the person has not been reckless - if HIV is transmitted despite the condom, it has been used in good faith and so there is no crime); and
 - v) the defendant transmitted HIV to the other person. Not only must it be proven that the complainant has contracted HIV, but it must also be shown that it was the defendant who transmitted the disease. The various medical and factual evidence required can include phylogenetic analysis of the strain of HIV, Recent Testing Infection Algorithm tests and serological testing, which are discussed further in the CPS guide.¹²²
- 8.13 It is a defence to a section 20 charge (reckless transmission) to show that the complainant has given informed consent to the assumption of risk of infection by engaging in sexual activity with a person who is infectious. Whether the complainant has consented is a matter for the jury to decide on hearing the facts of the case.¹²³
- 8.14 It is not possible to attempt to commit a section 20 offence. The charge of attempted transmission is reserved solely for the more malicious act of the attempt to intentionally transmit the disease. Therefore, a prosecution cannot be brought under section 20 unless transmission has actually taken place.¹²⁴ Furthermore, the defendant does not have to have directly told the complainant about the risk of infection to rely on the defence of consent. It is sufficient that the defendant can prove that a third party has informed the complainant of the defendant's condition. A complainant can also be considered "informed" if aware of certain circumstances that indicate that the defendant is suffering from a sexually transmitted disease (e.g. visiting the defendant while undergoing treatment for the infection in hospital).¹²⁵
- 8.15 So far, 20 cases have reached the courts in England and Wales. 13 individuals have pleaded guilty to the offence and the sentences have ranged between one year and 4.5 years. All of the cases were for reckless transmission; there have not been any successful prosecutions for intentional transmission, presumably

¹¹⁶ *ibid*

¹¹⁷ Reference to the Court of Appeal (Criminal Division) by the Attorney General under section 36 of the Criminal Justice Act 1972 (No 6 of 1980) [1981] EWCA Crim 1

¹¹⁸ Crown Prosecution Service Prosecution and Policy Guidance "Intentional or reckless sexual transmission of infection", page 12

¹¹⁹ *ibid*, page 4

¹²⁰ Crown Prosecution Service Guidance "Policy for prosecuting cases involving the intentional or reckless sexual transmission of infection", page 5

¹²¹ HIV and AIDS Information: transmission as a criminal offence - Introduction to the legislation

¹²² Crown Prosecution Service Prosecution and Policy Guidance "Intentional or reckless sexual transmission of infection", pages 5-7

¹²³ *Ibid*, page 4

¹²⁴ *Ibid*, page 11

¹²⁵ Crown Prosecution Service Guidance "Policy for prosecuting cases involving the intentional or reckless sexual transmission of infection", page 6

because of the difficulty in proving a defendant's intention to transmit HIV.¹²⁶

- 8.16 A victim of transmission of sexually transmitted diseases may also apply to the Criminal Injury Compensation Board for a payment for the injury suffered. One case has currently been reported in the sphere of the transmission of HIV, although this was not a case in which the disease was contracted through sexual intercourse, but rather as a result of suffering an assault. The Board must assess each case on its particular merits, but in this case it had no comparable cases for guidance. On hearing the merits of the case, the complainant was awarded a total of £82,484, which constituted payment for general damages (pain and suffering etc) as well as future loss of earnings.¹²⁷

SCOTLAND

- 8.17 We are not in a position to advise on Scottish law but we understand, however, that Scotland has slightly different laws to England and Wales and that HIV positive persons can be charged with the criminal offence of 'Culpable and Reckless Conduct' for situations where they put someone at risk of HIV transmission, notwithstanding that no transmission took place. The prosecution does not have to prove intent to transmit HIV, as they do in England; it is sufficient for the prosecution to show that a person has acted negligently, recklessly, or even indifferently by not taking any action to protect or lessen the impact on another. The Terrence Higgins Trust provides a useful guide on the law of Scotland.¹²⁸

9. Further Information

- 9.1 We have no further information to add.

Arnold & Porter (UK) LLP
April 2014

¹²⁶ HIV and AIDS Information: transmission as a criminal offence - Introduction to the legislation

¹²⁷ H (CICB: Quantum: 1998) (HIV), Re (1999) 99(4) Q.R. 8.

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Southern African AIDS Trust

REPORT

REGIONAL

2014



REVIEW -FRANCE

**HIV SELF-TESTING
REGULATION AND POLICY**



FRANCE

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1. Introduction/Background

- 1.1 For the purpose of this memorandum, “HIVST” refers to “expedited” HIV tests which are performed by the individual himself/herself and whose result can be read directly on the device itself after approximately 20 minutes (as opposed to laboratory blood tests which may only be performed in duly authorized medical labs).
- 1.2 For the time being, performance of expedited HIV tests is authorized in specific circumstances and under medical or social worker supervision. Expedited HIV tests performed under the conditions set forth in Section 2 below are referred to as “Tests Rapides d’Orientation Diagnostique” (decree dated 28 May, 2010 and decree dated 9 November, 2010).
- 1.3 The French Health Authority defines rapid diagnostic test as an unitary test with a subjective reading, of an easy use and conceived to give results in a short delay (generally 30 minutes). It may be performed with whole blood, saliva, plasma or serum according to the matrix claimed by the manufacturer for its product. The product enables to detect HIV-1/HIV-2 antibody.¹ Technically, an expedited HIV test (and later a HIVST) is defined as an in vitro diagnostic medical device which must comply with minimal technical specifications set out in the decision of the European Commission dated November 27th, 2009.
- 1.4 The French Health Minister, Marisol Touraine, recently announced that – subject to CE mark - in-home OTC tests will soon be available in French local pharmacies “for people who do not want to go to testing centers or hospitals (“unsupervised” self-testing).

2. Summary of advice

- 2.1 HIV tests are performed in France mainly by a full biological test in a medical lab. The French legislation authorizes as an exception the use of expedited HIV tests in certain circumstances but always under medical and/or trained social workers supervision. In consequence, for the time being, HIVST kits cannot to be sold to the general public. However, French Health Minister, Marisol Touraine, recently announced that in-home OTC test will soon be available in French local pharmacies for “people who do not want to go to testing centers or hospitals” and it is likely that some changes in national legislation will be implemented in the coming months.
- 2.2 In France, performance of HIV tests, including expedited HIV-testing, cannot be imposed on individuals, except in very specific situations and healthcare professionals supervising the test must obtain specific and informed consent from the tested individual and keep absolute medical confidentiality. It should be noted that the disclosure of the HIV test result – even if it is positive – is solely the responsibility of each individual and, in any event, discrimination against HIV-positive individuals is unlawful.

3. Is HIV self-testing legal and, if so, under what conditions?

- 1.1 HIV self-testing kits for use by the patient without medical supervision cannot currently be sold in France. The French Health Minister, Marisol Touraine, recently announced that – subject to CE mark - in-home OTC tests will soon be available in French local pharmacies “for people who do not want to go to testing centres or hospitals (“unsupervised” self-testing). The details of the planned changes to the law are not known. For the time being, performance of expedited HIV tests is authorized in specific circumstances and under medical or social worker supervision. The French National Agency for Medicines and Health Products Safety (ANSM) in a recent press release (12 February, 2013) indicated that, according to them, in Europe, the HIVST kits that can be purchased directly by patients do not satisfy applicable regulatory requirements in the European Union. The Agency noted that the assessment of HIVST kits by manufacturers is still on-going to ensure that before their commercialization the HIVST kits won’t compromise the clinical condition or the safety of patients and achieve the performances intended by the manufacturer.

¹ HAS, Recommandations en santé publique, Dépistage de l’infection par le VIH en France” October 2009, p.4

- 3.1 Performance of expedited HIV tests in certain urgent situations (when it is impossible to perform a full biological test in a medical lab) has been first authorized by a French Decree dated 28 May, 2010. This decree has authorized expedited HIV-testing (using capillary blood sample² – not saliva) under medical supervision and in the following circumstances:
- blood exposure incident (the person who is the “source” of the blood is the one to be tested)
 - sexual exposure incident
 - birth delivery (the test is proposed to the pregnant woman if her serological status is unknown or if she has been potentially exposed to the virus since her last test)
 - the test is urgently required to diagnose an acute pathology, which is symptomatic of AIDS.
- 3.2 The test can be performed under supervision by the following professionals:
- a physician in private practice, a physician or a biologist practicing in a hospital or a health service (*service de santé*)
 - a mid-wife practicing in a hospital or a health service
 - a nurse or a medical lab technician practicing in an hospital or a health service, under the responsibility of a physician or a biologist
- 3.3 The professional who supervises the test must ensure that the patient has consented freely to such test. The result of the test is communicated to the patient during an individual medical consultation.
- 3.4 Regardless of whether the result of an expedited HIV-test is negative or positive, it must be confirmed by a full blood test performed in a medical lab.
- 3.5 Another decree dated 9 November, 2010 authorized the performance of expedited HIV tests (on capillary blood) under medical supervision and/or the supervision of trained social workers in non-urgent situations. It should be noted that the decree of 9 November 2010 extends the scope of expedited HIV-testing and provides that it may be performed even when there is no urgency, provided it is done under the supervision of a healthcare professional or an authorized social worker.
- 3.6 This new decree has authorized performance of expedited HIV tests, in the interest and for the sole benefit of the patient, under supervision of:
- 3.7 The above professionals/persons³ have a duty to keep medical confidentiality (breach of medical confidentiality is criminally sanctioned – up to one year imprisonment and fine up to 1,500 euros – Article 226-13 of French Criminal Code).
- 3.8 The individual tested must receive adequate information and must specifically consent to the test. The testing device can only be used if it has received the CE mark in compliance with EU regulations (article 1 of decree dated 28 May 2010). After the expedited HIV-test has been performed, he or she is systematically invited to confirm the result by performing a full blood test in a medical lab.
- 3.9 It should also be noted that the *Conseil National du Sida*⁴ issued in March 2013 a positive opinion in favour of broadening the use of saliva HIVST kits. The French Minister of Health indicated that, subject to their obtaining of the CE mark, those kits should be available for sale to patients in local pharmacies within a few months. It is intended that those tests be authorized for use without medical supervision. To our knowledge, for the moment, no legislation has been passed concerning the sale of HIVST devices to the general public (only general declarations have been made in this respect by the French Minister of Health).

² i.e., blood obtained, for instance, from a fingertip

³ Performance of expedited HIV tests by any individual other than the above professionals is prohibited and may result in a claim for damages from the patient.

⁴ The Conseil National du Sida is an advisory body whose composition shall be such to allow for a comprehensive understanding of the problems posed by HIV and which shall be consulted for any information, or harm-reduction and education for health programs set up by the Government and public bodies and more generally may give opinions on the issues posed by HIV and make any proposals to the government.

4. What legislation governs the distribution of HIVST kits and what rules/conditions exist concerning this distribution?

- 4.1 For the time being, it is legal to sell/distribute expedited HIV-testing devices for use by healthcare professionals and/or trained social workers listed in decree dated 28 May 2010 and decree dated 9 November 2010. Several companies (e.g., Inverness, Servibio, Biomérieux) currently sell expedited HIV-testing devices (using capillary blood) for use by French healthcare professionals.
- 4.2 To be placed on the French market, the device must be CE-marked (Article 2 of decree dated 28 May 2010). However, said devices may only be used under the conditions set forth in French decrees dated 28 May 2010 and 9 November 2010, which are detailed in Section 2 above.
- 4.3 It is anticipated that, in the coming months, saliva HIVST kits are to be sold in local pharmacies for use by patients (without specific medical supervision). To our knowledge, for the moment, no legislation has been passed concerning distribution of HIVST in local pharmacies (only a general declaration has been made by the French Health Minister).

5. What are the human rights issues surrounding HIVST?

- 5.1 Human rights issues related to HIVST which have been identified by French authorities and consulting bodies (such as *Conseil National du Sida* and *Conseil National d’Ethique*) mainly concern freedom to consent to the test and confidentiality of the results. The ECHR and the Charter of Fundamental Rights apply to France.
- 5.2 It is a general principle under French law that individuals must specifically consent to any medical act/diagnostic (Article L. 1111-4 of the French Public Health Code - subject to limited exceptions – see below for HIV test).
- 5.3 In France, performance of HIV tests (either expedited HIV tests or tests performed in a duly authorized medical lab) cannot be imposed on the individual, except in very specific situations (donation of blood, organs, gametes, maternal blood) or if the concerned individual has a professional occupation where safety is critical (e.g., aircraft pilot).
- 5.4 The obligation to obtain specific and informed consent for expedited HIV-testing is set forth in Article 3 of decree dated 28 May 2010 and Article 1 of decree dated 9 November 2010.
- 5.5 The expedited HIV-test must be performed in a setting which guarantees confidentiality and privacy (decree dated 9 November 2010 – Annex I, Article 1.5). The healthcare professionals supervising the test must keep medical confidentiality (Article 3 of decree dated 9 November 2010 and Article 226-13 of French Criminal Code).
- 5.6 Does every person have a right to be tested?**
 - 5.6.1 In France, any individual has access to free and anonymous HIV testing. In particular, French law dated 30 July 1987 and implementation decree dated January 18, 1988 authorize performance of anonymous and free medical labs tests at the patient’s request. Those tests are performed in dedicated free and anonymous testing centers – “*centres de dépistage anonymes et gratuits*”).
 - 5.6.2 Also, any individual can access expedited HIV-testing provided the conditions detailed in Section 2 are met.
- 5.7 Can a person be compelled to make any disclosures concerning a positive diagnosis and, if so, in what circumstances?**
 - 5.7.1 Under French law, individuals tested cannot be compelled to disclose the diagnosis and the healthcare professionals supervising the test must keep medical confidentiality (Article 3 of decree dated 9 November 2010 and Article 226-13 of French Criminal Code).
- 5.8 Can a person be forced to take a test or compelled to have a child tested?**
 - 5.8.1 No, the individual tested (or his/her legal representative in the case of a child) must specifically and freely consent to the test (after having received adequate information - Article 3 of decree dated 28 May 2010 and Article 1 of decree dated 9 November 2010).
- 5.9 What is the law regarding discrimination based on a person’s diagnosis with HIV?**
 - 5.9.1 In France, pursuant to article 225-1 of French Criminal Code⁵, it is unlawful – in particular, for employers – to discriminate individuals on the basis of their serological status.
 - 5.9.2 However, insurers never have the obligation to provide insurance coverage and they can make their own assessment on the basis of the information provided (on a voluntary basis) by the concerned individual.

⁵ Discrimination is punishable before French criminal courts and may entail up to three years’ imprisonment and a fine of 45 000 € (article 225-2 of the French Criminal Code).

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 The manufacturer/distributor would be liable to the patient and/or to third parties if the product is defective and/or if a fault in the manufacturing/distribution of the device can be evidenced. The main grounds establishing the manufacturer/distributor's liability would be Articles 1386-1 et seq. of the French Civil Code (implementing Directive 85/374/CEE under French law) or Article 1382 of the French Civil Code (tort liability, fault-based regime), it being specified that those grounds are not specific to HIVST. The manufacturer/distributor may also be held liable if the device has been provided free of charge.
- 6.2 Health authorities may also decide to prohibit and/or suspend commercialisation of the test.

7. Further issues concerning HIV regarding consent, counselling, disclosure and confidentiality

- 7.1 Before the test is performed, the patient is to be informed that the test is just an indication of the diagnosis and that it will, in any case, need to be confirmed by a full blood test (performed in a medical lab).

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

- 7.2.1 As indicated at paragraph 5, the individual tested must specifically consent to the test but written consent is not required (Article 3 of decree dated 9 November 2010).
- 7.2.2 Failure by any of the professionals listed in points 3.3 and 3.7. to obtain the patient's prior consent may result in a claim for damages from the patient under tort. It may also constitute for health professionals a disciplinary offence⁶. In the case of a lay person who uses an HIV self-testing kit on someone without obtaining their consent, they would be liable to the individual for damages under tort and, if violence was used, they might also be criminally liable.

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

- 7.3.1 The legal age to give consent is 18. Parents/guardians have the authority to decide for their children who are under 18 (healthcare professionals are supposed to consult individuals under 18 even though it is their legal representatives who can make the final decision – Article L. 1111-4 of the French Public Health Code).

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

- 7.4.1 The results of the test are communicated to the patient during an individual medical consultation. During this consultation, the professional supervising the test must explain the limits of expedited HIV-testing in terms of reliability (Article 2 of decree dated 28 May 2010).

7.5 Confidentiality of test results

- 7.5.1 Test results are confidential and the healthcare professionals supervising such test are subject to medical confidentiality duties (Article 3 of decree dated 9 November 2010 – Article 226-13 of French Criminal Code).

7.6 Duties of disclosure to partner/employer/insurer

- 7.6.1 The law does not provide for any general duty to disclose to partner/employer/insurer (subject however to potential criminal liability in cases of HIV transmission to a partner).
- 7.6.2 Insurers can request information from the patient himself / herself but cannot obtain medical information directly from healthcare professionals (who are bound by medical confidentiality). If it can be evidenced that the patient has provided false information to the insurer, then the latter can consider that the insurance contract is not valid (Article L.113-8 of French Insurance Code).

8. What are the criminal implications of transmitting - or being reckless as to transmission of - HIV?

- 8.1 French courts have ruled that a person who has unprotected sex while he/she is aware of his/her serological status is guilty of intentional poisoning and is criminally liable (including through imprisonment) (CA Colmar – 4 January 2005, C. de Cassation – 10 January 2006). To our knowledge, there has been no court decision addressing specifically a situation where the defendant had discovered his/her HIV status through an expedited HIV-test but we can assume the same rule applies.

⁶ Employees or voluntary members of an entity involved in disease prevention mentioned in point 3.7 must also comply with good practices guidelines (including obtaining of patient's prior consent) set forth in Annex III of decree dated 9 November, 2010.

9. Further information

- 9.1 As indicated above, OTC home tests should be available soon in French local pharmacies (but to our knowledge this is not the case yet). In her declaration, French Minister of Health has not detailed envisaged changes to French legislation. She only indicated that the relevant devices will have to obtain a CE-mark. In its opinion dated 22 March, 2013, the *Conseil National du Sida* suggested that HIVST devices be made available to the general public in community pharmacies (without medical prescription being required), para-pharmacies⁷ as well as on the internet. These legislative changes can be followed on the Ministry of Health website (www.sante.gouv.fr) or on a specialized association website (<http://www.sida-info-service.org>).

10. References

- 10.1 Arrêté du 28 mai 2010 fixant les conditions de réalisation du diagnostic biologique de l'infection à virus de l'immunodéficience humaine (VIH 1 et 2) et les conditions de réalisation du test rapide d'orientation diagnostique dans les situations d'urgence - <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTXT000022320859&dateTexte=&categorieLien=id>
- 10.2 Arrêté du 9 novembre 2010 fixant les conditions de réalisation des tests rapides d'orientation diagnostique de l'infection à virus de l'immunodéficience humaine (VIH 1 et 2) <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023093746&dateTexte=&categorieLien=id>
- 10.3 Conseil National du Sida – Rapport sur les autotests de dépistage de l'infection à VIH (22 mars 2013)
- 10.4 <http://www.cns.sante.fr/spip.php?article466>
- 10.5 ANSM – Mise en garde relative à la vente actuelle d'Autotests VIH sur Internet (22 février 2014)
- 10.6 <http://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Mise-en-garde-relative-a-la-vente-actuelle-d-Autotests-VIH-sur-Internet-Point-d-Information/%28language%29/fr-FR>

Paris

20 May, 2014

⁷ A para-pharmacy is a company which can sell healthcare and hygiene products available without medical prescription (as cosmetics, some dietetic products) and with the exception of drugs.



Southern African AIDS Trust

REPORT

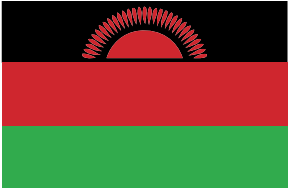
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2014



REVIEW - MALAWI

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



MALAWI

MALAWI

SAVJANI & CO

(VINCENT CHIKAONDA)



Savjani & Co.

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1. Introduction/Background

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

2. Summary of advice

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

3. Is HIV self-testing legal and, if so, under what conditions?

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

4. What legislation governs the distribution of HIVST kits & what rules/conditions exist concerning this distribution?

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

5. What are the human rights issues surrounding HIVST?

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

5.2 Does every person have a right to be tested?

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

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

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

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

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

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

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

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

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

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

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

6. What is the liability, to the patient and/or third parties, of a supplier if a kit is faulty/gives an inaccurate diagnosis? Is the answer different if a kit is sold rather than supplied free of charge?

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

7. Further issues concerning HIV regarding consent, counselling, disclosure and confidentiality

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

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

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

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

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

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

7.4 Confidentiality of test results

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

of the source client.

7.5 Duties of disclosure to partner/employer/insurer

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

8. What are the criminal implications of transmitting - or being reckless as to transmission of - HIV?

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

9. Further information

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

10. References

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



Southern African AIDS Trust

REPORT

REGIONAL

2014



REVIEW-MOZAMBIQUE

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



MOZAMBIQUE

MOZAMBIQUE

PIMENTA DIONÍSIO e ASSOCIADOS

(FILIPA RUSSO DE SÁ AND NEIDE CHANDE)



Pimenta, Dionísio e Associados
Sociedade de Advogados

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1. Introduction/Background

- 1.1 This memorandum was prepared for the sole benefit of the Southern African AIDS Trust (hereinafter “SAT”). It may not be relied upon by any person or entity without our express, prior written consent.
- 1.2 The purpose of this memorandum is to assist SAT in the understanding of the Mozambican legal framework relating to HIV self-testing.
- 1.3 The analysis and conclusions set out below are limited to the matters expressly stated herein, and no opinion may be inferred or implied beyond those expressly stated.
- 1.4 Mozambique is a republic with a semi-presidential constitutional democracy and multi-party system.
- 1.5 The domestic legal system is the Roman-German Civil Law or the Continental Law System, which was inherited by Mozambique from its former colonial power, Portugal. Most of the legislation in force in Mozambique (particularly the one that is codified) was also inherited from Portugal, although its interpretation is subject to the rules and principles set forth in the Mozambique’s Constitution.
- 1.6 After the official diagnosis of the first AIDS case in Mozambique, back in 1986, the Mozambican government engaged in an educational campaign on HIV/ AIDS through the Ministry of Health.
- 1.7 Between 1988 and 2009, the following programs/commissions were created/implemented:
 - 1988 – National AIDS Commission;
 - 1990 – HIV/ AIDS Epidemic Alert System;
 - 1994 – National Program for Contending STD/ AIDS, for the integration of the control of sexually transmitted diseases into the programs against HIV/ AIDS;
 - 1998 – Inter-Ministerial AIDS Commission and National Program to Contend AIDS;
 - 2000 – National Strategic Plan to Contend STDs/ HIV/ AIDS (PEN) (2000/2002);
 - 2000 – Action Plan to Contend HIV/ AIDS in Mozambique (Resource Requirements for 2001-2003);
 - 2001 – Action Plan for the Reduction of Absolute Poverty (2001-2005);
 - 2005 – Second National Strategic Plan (PEN II) (2005-2009).
- 1.8 Mozambique has also included some international rules regarding HIV/ AIDS in his domestic legislation.

2. Summary of advice

- 2.1 As per the client’s request, we analysed several legislation and prepared this memo in order to provide the client with information on several matters relating to HIV self-testing, such as its legality and possible distribution of the relevant kits, liabilities regarding defective products, amongst others.
- 2.2 In summary, the legality of distributing and undergoing testing with HIV self-testing kits for use at home is uncertain in Mozambique as there is no law specifically dealing with this matter.
- 2.3 Although the Mozambican authorities are not aware of existing HIV self-testing kits in the country, HIV testing is only carried out at national hospitals and/or private clinics.
- 2.4 Thus, the possibility of allowing self-tests, which are not referred to in any legislation, needs to be assessed with the Ministry of Health (“MISAU”), as well as the authorization for use of the relevant kits, due to its associated ethical, legal and social implications.

3. Is HIV self-testing legal and, if so, under what conditions?

- 3.1 There is only one regulation that expressly deals with HIV testing: the Regulation on HIV Counselling and Testing for the users of the National Health Service (Ministerial Order No. 201/ 2009, of 10 August 2009, hereinafter “**Regulation**”).
- 3.2 The Regulation does not contain any provisions or legal definition on HIV self-testing. Moreover, it is worth mentioning that according to the information gathered (on a non-name basis) from the Ministry of Health and some pharmacies and private clinics, self-testing kits (*disposable or home testing*) are not available in Mozambique.
- 3.3 Currently, there are mainly two types of HIV related tests available in Mozambique: (i) blood testing and (i) the so called “*rapid testing*”. Blood testing is performed free of charge before the National Health Service (state hospital) or, at a cost, before private clinics, hospitals and laboratories. The “*rapid testing*” is exclusively used by the National Health Service and involves the taking of a blood sample from a patient’s finger and dropping it into a solution that provides immediate results.
- 3.4 Do note that aside from the above, the National Health Service has also available another type of tests, which, despite being more comprehensive, is not commonly used as it is far more expensive than the two name above: the DNAPCR, normally used in children of HIV patients or in more sensitive cases.
- 3.5 Pursuant to the Law on the Rights and Duties of the Persons Living with HIV and AIDS, all laboratories and blood banks that perform HIV tests are required to be registered with the Ministry of Health and to maintain an updated system of registration and information available to the Sanitary Authorities.
- 3.6 Although the law is silent with regard to the legality of HIV ST, there is also no law prohibiting it. Thus, the actions referred to in section 4 should be taken into consideration when distributing HIVST. What legislation governs the distribution of HIVST kits & what rules/conditions exist concerning this distribution?

4. What legislation governs the distribution of HIVST kits and what rules/conditions exist concerning this distribution?

- 4.1 In order to trade and/or distribute products in Mozambique, one is required to obtain a business license from the Ministry of Trade and Industry (“MIC”) or a specific license issued by the Ministry responsible for the sector of activity in which such product is included, otherwise said trading and/or distribution shall be deemed as illegal.
- 4.2 Although there is no specific law on medical devices, same can be traded, distributed, imported and exported under a business license issued by MIC, provided that same are previously registered with MISAU.
- 4.3 Aside from the aforesaid business license, one needs to obtain MISAU’s prior authorization for importation and trade of the HIV ST kits. The HIV testing kit and/or self – testing kit is considered as a medicine pursuant to the Medicine Law. The definition in article 1(a) states that, amongst others, substances or compositions capable of establishing a medical diagnosis are also deemed as medicines. The Medicine Law states that all medicines and pharmaceutical products can only be imported and placed on the market in Mozambique if the same are registered with the MISAU.
- 4.4 Pursuant to article 18, of Decree no. 22/99 of 4 May, 1999, the interested party (which needs to be a company duly incorporated and registered in accordance with the Mozambican laws) needs to complete the relevant form, which should be submitted alongside with:
 - i) Technical-dossier of the pharmaceutical product;
 - ii) Certificate of registration and trading license from the country of origin, under the terms established by W.H.O, as per the Quality Certification System for Pharmaceutical Products in International Markets; and
- (i) Samples of the finished product in packages used in the country of origin;
- (ii) Proof of payment of due fee.
- 4.5 If deemed necessary, MISAU may request additional documents providing sufficient evidence of trials, studies and control, in order to obtain the necessary guarantees relating to the safety, effectiveness and quality of products submitted for registration.
- 4.6 MISAU will issue a license authorizing the entrance of said products in the Mozambican market and afterwards it will update the list of authorised products (according to the information gathered from MISAU, the list is usually updated quarterly). Said license is valid for a period of 5 years, which shall be renewed at least 180 days prior to its expiry date. One can obtain a copy of the medicines and pharmaceutical products authorized, provided that an application is submitted for said purposes, alongside with a blank CD.
- 4.7 Should the purpose consist in supplying ST Kits with no monetary consideration, the aforesaid registration with MISAU is still required and such supply could be achieved through agreements with MISAU and/ or with existing local or foreign NGOS. Alternatively, the interested party may request its registration as a foreign

NGO, at the Ministry of Foreign Affairs and Cooperation ("MINEC"), and supply the ST Kits itself.

- 4.8 Exceptionally, in very specific situations, the MISAU may authorize the importation of products not previously listed on the list of medicines and pharmaceutical products registered with MISAU (a copy of the list may be obtained from MISAU). The documents required to obtain this authorization are less in number and in complexity¹ and although MISAU did not provide us with any specification on its timeframe, we were informed that the process to obtain an exceptional authorization is less time consuming than the normal process, which can take up to a year to be finalized. Even if an exceptional authorization is granted, the product is not automatically registered at MISAU. The importer shall have to subsequently request the registration of said product at MISAU and the relevant procedures and documents do not differ from those requested for the issuance of a normal authorization.

With reference to the specific situations, the Law only states that non-registered products can be authorised on an exceptional basis in two circumstances: (i) whenever a product is deemed essential to a treatment or the diagnosis of certain pathologies i.e. public health is at stake, and provided that the practitioner provides MISAU with detailed information on the reasons for requested such product; and (ii) whenever the product is to be exclusively used in research and clinical trials, provided that MISAU has previously approved the intended research protocol. Unfortunately, we cannot confirm whether MISAU would need to make an exception for HIV self-testing kits as MISAU's position can only be confirmed following the submission of the documents required for the registration of the ST kits. However, in light of the above, please bear in mind that it is our understanding that the importation of the HIV self-testing kits does not seem to be included among the grounds for an exceptional authorization.

- 4.9 Devices used by public hospitals are purchased in accordance with the provisions set forth in Law no. 15/2010, of 24 May 2010 (which approves the Regulation on Procurement of Public Works and Supply of Goods and Services to the State). Pursuant to this law, the general rule of procurement of goods for Governmental Institutions is by public tender and the assessment criterion is based on the lowest price. This law is only applicable to government's purchases, thus, it does not have any relation nor can be used in matters connected w/ HIV ST Kits purchased by private bodies or individuals.
- 4.10 According to the information gathered (on a non-name basis) from MISAU, when the national health service purchases medical devices, the main criteria consists in ensuring that such products are W.H.O accredited.
- 4.11 The question of legislative change can only be taken into consideration after MISAU's (eventual) refusal to authorize the distribution of ST Kits, whether for free or not. In such case, one could try to discuss the grounds for the refusal with MISAU in hope of a change of opinion.
- 4.12 Laws, decree-laws, decree, resolutions and ministerial orders can, at any time, be created/ amended through the appropriate channels, in order to accommodate matters that despite being important are not contemplated in any legislation. The procedures, timing and complexity shall depend on the entity with powers for said creation or amendment.
- 4.13 Since the distribution of ST Kits falls under MISAU's umbrella, should it be necessary to include matters in existing legislation and/or create specific ones, one could expect MISAU to propose the issuance of a law, decree-law or decree, to the Parliament or to the Council of Ministers.

5. What are the human rights issues surrounding HIVST?

5.1 Does every person have a right to be tested?

- 5.1.1 The Mozambican Constitution establishes the general right to health, comprised by the right to medical and sanitary assistance. This is an absolute right. Under the Mozambican Constitution, the State is responsible for providing medical and sanitary assistance to its citizens through a national health system. Thus, MISAU, through its National Medical Assistance Directorate, is responsible for the management of the national health system.
- 5.1.2 Moreover, it is worth mentioning that medical and pharmaceutical assistance to HIV patients is free of charge in this system.
- 5.1.3 Please note that we are unable to ascertain whether this right has been infringed.

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

- 1.1.1 The Law on the Rights and Duties of the Persons Living with HIV and AIDS expressly forbids practitioners or any health official to disclose HIV tests results to non-authorized third parties. The results can only be disclosed to the person taking the HIV test or to his/her parents in case such person is a minor.

¹ One is only required to submit an application to MISAU, stating the following: the product's commercial and generic name; its dosage and pharmaceutical formula; the customs office, consignor and consignee; place of origin; and the required quantity.

- 1.1.2 The General Principles of Protection Against Discrimination of Employees or Candidates and in employing people living with HIV/ AIDS, also expressly forbid HIV/ AIDS testing on employees or candidates when requested by the employer without their prior consent.
- 1.1.3 The employee's confidentiality right is also stipulated therein, granting him/her the following rights:
 - the right of non-disclosure of his/her condition to third parties in the place of work; and,
 - the right of non-disclosure of his/her condition to the employer without his/her consent.

- The confidentiality right is also applicable to health officials that may be aware of the employees' condition.

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

- 5.3.1 Although there are no references to HIVST, Article 25(1) of the Law on the Rights and Duties of the Persons Living with HIV and AIDS establishes the prohibition of HIV testing without prior consent as well as the exceptions to such rule and the subsequent article stipulates that counselling and testing should be offered to pregnant women and/or same can request it as part of pre-natal care. Moreover, its article 28 refers that the State acknowledges and allows, among the several testing for HIV, the counselling and testing requested by users of the sanitary unit (ATIU).
- 5.3.2 The statute stipulates that HIV Tests can only be performed with the person's prior consent, except if:
 - i) the practitioner deems HIV test necessary exclusively for the patient's health and treatment;
 - ii) related to blood or blood components, maternal milk, organs and human tissues donations²; or
 - iii) tests are required for criminal proceedings/investigations, provided that there is a prior judicial ruling in this regard.
- 5.3.3 The aforesaid statute also provides that HIV tests in minors can only be performed with their parents' prior authorization. However, said authorization is excluded in the situations referred to in paragraphs (i) to (iii), above. See section 7.2 for more information on minors.

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

- 5.4.1 In Mozambique, the following internal legislation expressly forbids the discrimination based on a person's diagnosis with HIV:
 - Constitution of the Republic of Mozambique – Principle of Universality and Equality;

Law on the Rights and Duties of the Persons Living with HIV and AIDS – forbids discrimination and mistreating of any person that lives with HIV;

Employment Law – establishes, among other principles, the principle of the right to work, of employment and job stability, and of non-discrimination on grounds of sexual orientation, race or HIV/AIDS;

General Principles of Protection Against Discrimination of Employees or Candidates and in employing people living with HIV/ AIDS – aims to ensure that all workers and job applicants are not discriminated in their workplaces or when applying for job positions for suspicion of being HIV/AIDS carriers.

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 The Regulation is silent in this regard. However, the Mozambican (i) Consumer Defence Act (Law No. 22/2009, of 28 September 2009) and (ii) Civil Code, contains general provisions on liability due to faulty goods and/ or inaccurate information.
- 6.2 The information below on the Consumer Defence Act, which is only applicable in cases of sale of goods, relates to the consumer right to be compensated from damages arising from defective goods, whether such consumer is the immediate purchaser of the product or not. The Civil Code's specific provisions on Sale and Purchase Agreements do not contain any references of the extension of said rights to third parties. However,

² Since article 13(2) of the Law on the Rights and Duties of the Persons Living with HIV and AIDS stipulates that such persons are proscribed from donating their blood or blood components, breast milk, organs and human tissue, except if for scientific investigation purposes, the HIV test can be made in this circumstances without their prior consent. This exception is indicated in paragraph b, of its article 25(1).

said code has general provisions on non-contractual liability and the provisions therein may also apply to third parties who are affected by an inaccurate diagnosis.

Third Parties

- 6.3 The Civil Code contains a general principle, whereby anyone who intentionally or recklessly (carelessness and negligence) violates a third party right or any legal provision that protects third party rights has to compensate the injured party for the damages arising from the infringement. Based on this general principle (and provided that sufficient evidence is presented), the affected party will be able to seek moral and/or monetary compensations. The following scenario is an example of a situation where an inaccurate diagnosis could lead to a claim by a third party against the supplier:

A and B have recently married and are thinking of expanding the family. A already tested for HIV at a public facility and his results were negative. Since B was not comfortable with going to a private and/or public facility in order to do the test, she purchases an HIVST Kit on her way home. After testing, B has a false negative result.

Based on the results of the HIVST kit, A and B decide to have unsafe sex, as both assume that no additional precaution needs to be taken in order to procreate.

Two months later, B discovers that she is pregnant and both go to hospital in order to undergo exams. The doctor advises B to also take an HIV test. B mentions that she has already taken one and the result was negative but she accepts to take another test anyway.

The results show that the HIVST kit had produced a false negative result. As a precautionary measure A asks to be retested and the results show that he has become infected.

A can seek moral and/or monetary compensation from the manufacturer due to the damages to his health. He can argue that if it were not for the result from the HIVST kit, he and B would not have had unsafe sex and he would have not been infected.

- 6.4 A third party would need to explain the reason why this General principle is being relied on to bring the claim. The claimant must also identify the legal right that was violated by the supplier and provide sufficient evidence that he/she suffered damage as a consequence. The relevant legal rights will vary case by case depending on the circumstances of each case. Depending on the facts, an inaccurate result from a self-testing kit could violate the constitutional right to health.
- 6.5 Consumers who purchase HIVST kits can rely on the General Principle if there is no specific provision providing relief under alternative legislation. However, the Consumer Defense Act specifically provides for consumers and, in most cases, this will be the appropriate basis for bringing an action against a supplier.

Consumer Defence Act (hereinafter referred to as “CDA”)

- 6.6 Under the CDA, in general terms, entities included in the production and trading chain of goods or services being sold or provided to consumers are under the obligation to:
- i) place goods in the market that do not bring any risks to the health or safety of consumers, except those that are deemed normal and expected due to their nature and use;
 - ii) provide adequate information on the goods/services regarding its characteristics, quality, amount, make-up, price, warranty, origin, and risks;
 - iii) guarantee the quality and working condition for a minimum period of 12 months for non-consumable moveable assets, which means that parties may agree to extent the warranty but not limit it;
 - iv) indemnify consumers for damages caused by defective goods/services. As a rule, those entities are joint and severally liable for the aforementioned obligations.
- 6.7 Further to our comments in paragraph (d), above, liability is applicable to all entities in the consumer chain i.e. entities carrying out activities of production, manufacturing, importation, construction, distribution and marketing of goods for consideration. Thus, whenever it is impossible to identify the producer, manufacturer or importer, the seller cannot exclude its own liability.

Information Requirements

- 6.8 The CDA requires consumers to be given clear, objective, and adequate information on all of the characteristics of any good or service purchased (including its price), as well as on the terms of the purchase agreement, any warranties, delivery deadlines, and any customer support provided after the sale. In particular, health and safety risks that may result from the good/service must be informed to the consumer.

- 6.9 The CDA further requires any information provided to consumers to be in Portuguese. This requirement covers any details about the characteristics, quality, amount, make-up, price, warranty, origin, and risks of any goods or services provided.
- 6.10 Entities involved in the production and trading chains of goods or services being sold or provided to consumers in Mozambique must provide (i) adequate information on the goods/services regarding their quality, technical features, price and risks involved in their utilization and (ii) guarantee the quality and working condition for a minimum period of 1 year for moveable non-consumable assets. This means that the parties may agree to extend the warranty, but not to limit it.
- 6.11 With regard to the lack of information, the CDA sets forth that consumers are entitled to return the good or service and be reimbursed for its price within 7 days as of receipt of the goods or execution of the services contract, whenever product information is not made available on adequate terms and such lack or shortage of information compromises the utilization of the good/service. In addition, entities providing goods/services in these circumstances are liable for any damages caused to consumers wishing to return the good or service.

Defective goods/services

- 6.12 Entities selling defective goods are required to remedy the defects within a period of 30 days. Service providers are liable for any quality defects or others which diminish the value of the service. Otherwise, consumers are entitled to:
- i) request the replacement of the good or the repeated provision of the service;
 - ii) reimbursement of the price paid for the goods/services (without prejudice to claiming damages); or
 - iii) request the reduction of the price paid for the goods. The re-execution of the services may be requested to a third entity, the costs of which shall be borne by the initial service provider.
- 6.13 Additionally, consumers may be entitled to claim damages as described below. Defects on goods or services must be claimed within a period of 30 days (for movable goods) as of the date the consumer became aware of the defect.

Damages

- 6.14 Entities selling goods/services that are defective or present features which do not correspond to those that have been advertised are required to indemnify consumers for damages arising from the supply of the good/service, except in cases where the consumer or any third party should be deemed exclusively liable for the damages occurred. This compensation is due regardless of any negligence or wilful misconduct of the entities providing the relevant goods/services.

Refunds and statutory cancellation rights

- 6.15 Pursuant to the CDA, a consumer has a right to withdraw from a contract for goods or services within seven days of receiving them whenever the agreement is entered into outside of a commercial establishment. Any amounts paid under the agreement must be returned.
- 6.16 Furthermore, the CDA grants consumers the right to rescind a sales agreement and demand a refund whenever a defective good is not repaired within 30 days of a complaint being made by the purchasing consumer.

Supplier Concept

- 6.17 The CDA applies to all entities in the consumer chain, i.e. entities carrying out activities of production, manufacturing, importation, construction, distribution and marketing of goods or rendering of services to consumers for consideration. The wording of the law usually refers to the provider of the service or of the goods (the seller) and clearly states that in those cases where the constructor, the producer or the importer may not be identified, the seller may not exclude its own liability.

Applicability

- 6.18 The CDA is applicable to entities involved in the production and trading chain of goods or services sold or provided to consumers. For the purposes of the CDA, a "consumer" is defined as any person to whom goods are provided, services are rendered, or rights are given, for non-professional use, by another acting in the course of a professional economic activity for gain.

Mozambican Civil Code

- 6.19 Further, the Mozambican Civil Code (“**CC**”) sets forth various general rules (not exclusive to consumer relationships) on sale of defective goods, granting certain rights and remedies to the buyer when the goods sold:
- i) Suffer from a defect which implies a reduction in their value;
 - ii) Suffer from a defect which prevents their use for the purpose they were manufactured and are commonly used;
 - iii) Do not possess the qualities claimed by the seller; or
 - iv) Do not possess the qualities necessary to serve the purpose they were manufactured and purchased for.
- 6.20 In the above cases the buyer is entitled to, alternatively:
- i) Have the good repaired;
 - ii) Have the good replaced, if necessary and if the good can be freely replaced by another good of the same kind;
 - iii) Terminate the contract and receive a compensation for damages; or
 - iv) A reduction in the price in case seller produces evidence that the buyer would have bought the goods with the defects that impair their full enjoyment, but at a lower price.
- 6.21 The remedies referred to in (i) and (ii) above do not apply if the seller did not know the defect or lack of quality, provided said lack of knowledge is not due to seller’s fault.
- 6.22 If the lack of qualities or defects can only be attributed to simple error on the part of the seller:
- i) Damages for loss of profits are expressly excluded (i.e. those benefits that were not gained as a consequence of the unlawful action or omission) meaning that immediate damages suffered, e. g. diminished value of the defective product; physical consequences of the use of the defective product, etc. are still subject to be compensated by the seller;
 - ii) Damages are completely excluded if the vendor was not aware without fault that the product was defective or lacked qualities i.e. all and every damage that the client may have suffered for having purchased a defective product, including immediate damages and loss of profits. The CC sets forth a presumption of fault for the vendor of defective products, which means that the vendor of defective products has to prove he did not act with fault in order to avoid liability and having to compensate the client. In practice, such proof will be very difficult to make.
- 6.23 The buyer must file a complaint with the seller within 30 days of the buyer gaining knowledge of the situation, and within 6 months of delivery of the goods, unless the seller acted with wilful misconduct in which case no notice is necessary.
- 6.24 The minimum warranty period – which is not specific for a consumer and is overruled by any provisions of the CDA – is 6 months, counting from the delivery of the product to the customer. This warranty period cannot be excluded or limited by agreement of the parties.
- 6.25 Furthermore, the purchaser may claim either the repair or replacement of the product in case the vendor is obliged, by agreement between the parties or by custom and usage, to warrant that the product functions properly, regardless of whether there is fault of the vendor or error from the purchaser. This warranty may be excluded by parties. If the contract is silent, an implied warranty of 6 months or other that follows from market practice applies. Within the warranty period the client shall notify the vendor of any defect no later than 30 days of finding the defect.
- 6.26 It must be noted that all the above warranties do not apply in case of normal wear and tear or misuse.
- 6.27 On the other hand, whenever goods are supplied free of charge, the donor cannot be held responsible for the damages arising from defective goods, except if same have expressly undertaken such responsibility or have had a wilful misconduct.

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 Article 25(1) of the Law on the Rights and Duties of the Persons Living with HIV and AIDS establishes the prohibition of HIV testing without prior consent as well as the exceptions to such rule. Please refer to question 5. 3 above which describes the circumstances in which consent is not required. Do note that the law only demands for “consent”, not specifying if it is written or not. Nonetheless, and in order to avoid any doubt, most of the private clinics in Maputo require patients to sign a written consent form before being submitted to HIV testing. The form has a brief explanation on how tests are performed and what help can be sought or is available should the result be positive.
- 7.1.2 Although this law fails to stipulate a consequence for the testing without consent, the General Articles of the State's Officers and Agents (EGFAE) – approved by law no. 14/2009 of 17 March, 2009 – states that officers are required to comply with all applicable legislation during the performance of their services. As such, should any medical officer perform the testing in breach of the stipulated in article 25(1) of the Law on the Rights and Duties of the Persons living with HIV and AIDS, the same can be subject to disciplinary proceedings, which can culminate with a disciplinary sanction (from a mere reprimand to expulsion).
- 7.1.3 Aside from that, civil actions may also apply, based on the principle referred to in paragraph 6.3., above. What is the legal age to give consent and what powers do parents/guardians hold in relation to consent process?

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 Mozambique a person is deemed minor until the age of 21. The Law on the Rights and Duties of the Persons Living with HIV and AIDS provides that HIV tests in minors can only be performed with their parents' prior authorization, which must be informed on the reasons for conducting such testing. However, said authorization is excluded in the situations referred to in section 5. 3, above. Do note that for minors from 16 to 21 years old, HIV tests may be performed with their acceptance, regardless of their parents' authorization.

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

- 7.3.1 As mentioned in paragraph 3.1., above, Ministerial Order No. 201/ 2009, of 10 August 2009, governs the HIV Counselling and Testing for all users of the National Health System.
- 7.3.2 Do note that counselling is also done by the National Health System before HIV testing in order to prepare the person for an eventual positive result and if positive, the post-counselling is free of charge. Additionally, pursuant to the Law on the Rights and Duties of the Persons Living with HIV and AIDS, HIV citizens benefit from free health care in all National Health System.
- 7.3.3 There are no specific rules concerning the provision of counselling to those with positive diagnosis when the test is performed in private clinics. We are aware that some private clinics offer post-counselling for positive diagnosis, upon patient's request. However these are not free of charge.
- 7.3.4 The Ministerial Order does not contain any information on the required standard of the counselling. However, same refers to the requirements and types of counselling.
- 7.3.5 With reference to the requirements, article 8 of said Ministerial Order states that the counselling process involves: (i) the presence of an health care provider / counsellor and the beneficiary user, (ii) a confidential dialogue, and (iii) privacy and confidentiality of the information obtained in said dialogue.
- 7.3.6 It is further mentioned that such counselling process aims to capacitate the user with knowledge on the risks of transmission, promotion of positive behaviours, emotional support for the taking of the test or for the decision-making subsequent to the test.
- 7.3.7 With regards to the types of counselling, the Ministerial Order stipulates two: the one that is given prior to the testing (“prior-testing”) and the one given afterwards (“post-testing”).
- 7.3.8 Pursuant to article 10 of the Ministerial Order, Prior-testing counselling is the confidential dialogue between the health care provider / counsellor and the user on his/hers health condition with regards to HIV and AIDS, in which the risk of transmission, his/hers apprehensions, doubts and the implications of possible outcomes are assessed so that the user can consciously give his/hers consent for the HIV testing. This counselling can either be individual or collective (for couples, families, group education and pregnant women in pre and post natal consultations).

- 7.3.9 Article 11 of the Ministerial Order stipulates that Post-testing counselling corresponds to the confidential dialogue between the health care provider / counsellor and the user on his/hers health condition with regards to HIV and AIDS, in which the result of his/hers test is explained to him/her. An immediate plan of life is made, references to emotional, social and clinic support are given, as well as an orientation towards the disclosure of his/hers clinical condition. Preventive measures are also emphasized. This counselling can either be continuous and of a follow-up nature (applicable to HIV positive users, in order to provide them medical care as well as institutional, emotional, and social support) or monitored (applicable for non-positive HIV users to positively influence their way and habit of life and reinforce the preventive measures).

7.4 Confidentiality of test results

- 7.4.1 The results of the HIV tests are strictly confidential. Inclusively, the Law on the Rights and Duties of the Persons Living with HIV and AIDS stipulates that anyone that reveals the confidential records of a HIV test result, to which accessed by means of his/hers professional duties, will be punished with a 1 year imprisonment and subject to fine in the amount up to six months.

7.5 Duties of disclosure to partner/employer/insurer

Partner

- 7.5.1 Pursuant to article 13(1.g), of the Law on Rights and Duties of Persons Living with HIV/AIDS, persons living with HIV/AIDS have, amongst others, the obligation of informing their spouse or sexual partner about their HIV condition.

Employer

- 7.5.2 With regards to employers, the Law no. 5/ 2002, of 13 February, 2002 (which approves the General Principles of Protection Against Discrimination of Employees or Candidates and in employing people living with HIV/AIDS) stipulates, in its article 6(1), that employees cannot be forced to inform their HIV status to the employer.
- 7.5.3 Having said that, please note that the Labor Law stipulates, in article 104 (1), that if an employee is absent from work for an uninterrupted period of more than 15 days due to illness, the employer can present him/her to the Board of Health (which is composed by practitioners from MISAU) or to other licensed body, in order to obtain a ruling on his/hers capacity to work. Employees that have their productivity affected due to health reasons or that, due to illness, are absent from work for more than 5 interrupted times for each trimester, can also be presented to said Board for the same purposes.
- 7.5.4 Furthermore, since employees cannot be dismissed based on their HIV status, pursuant to article 9 of the General Principles of Protection Against Discrimination of Employees or Candidates and in employing people living with HIV/AIDS, employers are required to train and reorient the employee that, being infected with HIV, is unable to perform his/hers job functions, giving him/her a job compatible with his/hers residual capacity. The law is silent as to whether the employee would need to disclose his/her HIV status in order for the employer to accommodate the employee. However, one may assume that such disclosure would have to occur at some point (either by the employee or, if the employee is submitted to the Board of Health, by the Board), so that the employer can comply with its training and reorientation obligation.

Insurer

- 7.5.5 Pursuant to Law no. 1/2010 of 31 December, 2010 (which approves the Insurance Legal Framework) the parties are subject to an information duty. With reference to the policy holder, such duty implies that he/she needs to provide the insurance company with all information and facts that he/she may or should be aware of, which may influence the insurance company's assessment of the risk.
- 7.5.6 In case of health insurance, should the policy holder fail to provide the relevant information, such as his/hers HIV status, the insurance company is entitled to terminate the insurance agreement due to breach of the information duty.

8. What are the criminal implications of transmitting - or being reckless as to transmission of - HIV?

8.1 The Law on the Rights and Duties of the Persons Living with HIV and AIDS establishes the following criminal implications for HIV transmission:

- i) If anyone knowing his/hers HIV status intentionally transmits it to others, same will be punished with 2 to 8 years imprisonment;
- ii) Such punishment will also be applicable to whom, being reckless, transmits the HIV to others.

8.2 In case someone, even by negligence, transmits the HIV in mass, using any kind of transmission process, excluding sexual transmission, such person will be punished with 8 to 12 years imprisonment.

8.3 The following facts are also deemed criminal offenses by the referred statute and subject to penalization:

- i) Discrimination – depending on the circumstances it can be punished with a 3 months' imprisonment and a fine in the amount up to one month;
- ii) Unauthorized publication of the image of a person that is HIV positive without his/hers consent – punished with imprisonment and fine;
- iii) Libel, defamation or slander – punished with up to 1 year imprisonment and fine in the amount up to six months;
- iv) Providing third parties with confidential information regarding HIV results – punished with up to 1 year imprisonment and fine in the amount up to 6 months; and
- v) Falsifying HIV tests results – 2 to 8 years imprisonment.

8.4 Although the above, we were not able to determine whether there is any criminal case regarding this type of crime.

9. Further information

- 9.1 Since the Mozambican law is silent regarding HIV self-testing, in order to safeguard the importer's position, we believe that it would be wise to submit an application to MISAU requiring its authorization for the importation and trade of such tests, before importing same. Said application should provide along with all necessary information regarding the composition and usage of the self-testing kits.
- 9.2 We hope the above to be of assistance and remain at your entire disposal to clarify and/or further discuss any aspect of our advice.

Pimenta Dionísio e Associados

April 2014

10. References

- 10.1 Please find below a list of the current domestic legislation addressing (directly or indirectly) issues relating to HIV/ AIDS:
- 10.1.1 Constitution of the Republic of Mozambique (2004);
 - 10.1.2 Resolution No. 44/ 2009, of 19 August 2009 – Strategy of Response to HIV/ AIDS in Public Servants;
 - 10.1.3 Resolution No. 73/ 2008, of 30 December 2008 – Strategy to Accelerate the Prevention on HIV;
 - 10.1.4 Resolution No. 27/ 2000, of 31 October 2000 – ratifying the SADC Protocol on Health;
 - 10.1.5 Law No. 12/ 2009, of 12 March 2009 – Law on the Rights and Duties of the Persons Living with HIV and AIDS;
 - 10.1.6 Law No. 23/ 2007, of 1 August 2007 – Employment Law;
 - 10.1.7 Law No. 5/ 2002, of 13 February 2002 – General Principles of Protection Against Discrimination of Employees or Candidates and in employing people living with HIV/ AIDS;
 - 10.1.8 Law No. 4/ 98, of 14 January 1998 – Medicine Law;
 - 10.1.9 Decree No. 22/ 99, of 4 of May 1999 – Regulation on the National System for Medical Registration;
 - 10.1.10 Ministerial Order No. 201/ 2009, of 10 August 2009 – Regulation on HIV Counselling and Testing for the users of the National Health Service;
 - 10.1.11 Governmental Policy about the Health National System for the Assistance and Treatment of People Living with HIV/ AIDS (2001).



Southern African AIDS Trust

REPORT

REGIONAL

2014



REVIEW -SOUTH AFRICA

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



SOUTH AFRICA

SOUTH AFRICA

NORTON ROSE FULBRIGHT SOUTH AFRICA

(INCORPORATED AS DENEYS REITZ INC)

(ROBERT DRIMAN, DANIEL MCCONNELL, INA GUEORGUIEVA, JONATHAN JONES)

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 of advice

- 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.
- 5.2.1 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.

- 6.7.67. 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

- 10.1 Broude v McIntosh and Others 1998 (3) SA 60 (SCA)
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- 10.4 Consumer Protection Act, 68 of 2008
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- 10.5 Children's Act, 38 of 2005
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- 10.6 Criminal Law (Sexual Offences and Related Matters) Amendment Act, 32 of 2007
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- 10.7 Criminal Procedures Act, 51 of 1977
(<http://www.justice.gov.za/legislation/acts/1977-051.pdf>)
- 10.8 Employment Equity Act, 55 of 1998
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- 10.9 Medicines and Related Substances Control Act, 101 of 1965
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- 10.11 The Constitution of the Republic of South Africa, 108 of 1996
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- 10.13 Promotion of Equality and Prevention of Unfair Discrimination Act 4 of 2000
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(http://www.hpcsa.co.za/downloads/conduct_ethics/rules/ethical_guidelines_good_practice_hiv.pdf)
- 10.15 Good Pharmacy Practice (GPP) standards, 2010, Section 2.13.5.8(h)
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Southern African AIDS Trust

REPORT

REGIONAL

2014



REVIEW-TANZANIA

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



TANZANIA

THE UNITED REPUBLIC OF TANZANIA

NEXUS ATTORNEYS

(JOHN MAGOTI)



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1. Introduction/Background

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

2. Summary of advice

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

3. Is HIV self-testing legal and, if so, under what conditions?

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

4. What legislation governs the distribution of HIVST kits and what rules/conditions exist concerning this distribution?

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

5. What are the human rights issues surrounding HIVST?

5.1 Does every person have a right to be tested?

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

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

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

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

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

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

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

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

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

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

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

6. What is the liability, to the patient and/or third parties, of a supplier if a kit is faulty/gives an inaccurate diagnosis? Is the answer different if a kit is sold rather than supplied free of charge?

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

7. Further issues concerning HIV regarding consent, counselling, disclosure and confidentiality

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

- 7.1.1 Yes, according to Section 15 of the Act there must be informed consent. Informed consent means the voluntary agreement of a person to undergo or be subjected to a procedure based on full information, whether such agreement is written, conveyed verbally or indirectly expressed (Section 15 of the Act).
- 7.1.2 Section 15(7) makes it an offence for a health practitioner to compel a person to undergo HIV testing or procures another person to undergo HIV testing without the knowledge of that other person. The actual penalty is under section 50 as quoted below:

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

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

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

- 7.2.1 The legal age to issue consent is 18 years old.
- 7.2.2 In accordance with Section 15, a child or a person with inability to comprehend the result may undergo HIV testing after a written consent of a parent or recognized guardian.
- 7.2.3 As per section 16, the results of an HIV test shall be confidential and shall be released only to the person tested. However, the results of an HIV test may be released to (a) in case of a child, his parent or recognized guardian; or (b) in case of person with inability to comprehend the results, his spouse or his recognized guardian.

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

- 7.3.1 Sections 13 and 14 of the Act stipulate that for the purposes of facilitating HIV testing, every public HTC health care facility and voluntary counselling centre recognized by the NACP shall be an HIV testing centre for the purpose of this Act. Therefore the Private Health Laboratory Board may, by Order publish in the Gazette, accredit any private laboratory to be an HIV testing centre.
- 7.3.2 Pre and post-test counselling for the patient is a mandatory condition for the provision of testing in HIV testing centres. During the pre-test counselling session, the client is prepared for the test by a Counsellor to receive pertinent information on HIV/AIDS and assess his/her readiness to take the test. The client is also given the opportunity to consider the meaning and impact of the test results on his/her life. Post-test counselling takes place after the test for HIV has been done. After being tested, the client is counselled again to prepare him/her to receive and cope with the test results. In this counselling session the Counsellor will also work with the client to develop a risk-reduction plan for those who test negative and steps that the client can take to live positively for those who test positive (National Guidelines for Voluntary Counselling and Testing, 2005).

7.4 Confidentiality of test results

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

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

7.5 Duties of disclosure to partner/employer/insurer

Partner

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

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

Employer

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

Insurer

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

8. What are the criminal implications of transmitting - or being reckless as to transmission of - HIV?

8.1 Section 47 of the HIV and AIDS (Prevention and Control) Act, 2008 states that "Any person who intentionally transmits HIV to another person commits an offence, and on conviction shall be liable to imprisonment for a term of not less than five years and not exceeding ten years".

8.2 There are several successful cases regarding the criminalisation of willful transmission of HIV AIDS in Tanzania that are "unreported". An example is at this link: <http://jabashadrack.blogspot.com/2012/11/mwanza-two-get-life-in-prison-for.html>. The case was based on two counts (a) defilement under SOSPA and (b) transmission of HIV AIDS to a minor.

9. Further information

9.1 Section 51 provides a mechanism of lodging a complaint against the contravention of this Act. That any complaint against contravention of any provision of this Act may be lodged in writing to -

- a) The Secretary to the village, ward, district or urban AIDS Committees as the case may be;
- b) The police station;
- c) The owner, manager or the person in-charge of a health care facility concerned; or
- d) The employer.

9.2 That every complainant shall be required to give all the necessary information in relation to the complaint in question.

9.3 And that the Minister may make regulations prescribing the mode of lodging and handling of complaints under this Act. To our knowledge the regulations are not in place.

10. References

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



Southern African AIDS Trust

REPORT

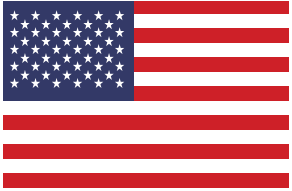
REGIONAL

2014



REVIEW -USA

**HIV SELF-TESTING
REGULATION AND POLICY**



USA

UNITED STATES OF AMERICA

ARNOLD & PORTER (USA) LLP

(DAN KRACOV, MATTHEW FORNATARO, LAUREN HAERTLEIN, ABEBA HABTEMARIAM)

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1. Introduction

- 1.1 The purpose of this memorandum is to provide Southern African AIDS Trust (“SAT”) with information and guidance as it explores options for promoting and implementing HIV self-testing in sub-Saharan Africa, Botswana, Malawi, Mozambique, Tanzania, Zambia and Zimbabwe. Although rapid HIV self-testing has not been widely implemented in many countries, the United States approved the first such test for home use in 2012. To inform SAT’s work in Africa, this memorandum therefore outlines the U.S. system for regulating HIV self-testing and the process by which self-testing was approved. Policy arguments for and against self-testing are also presented.
- 1.2 Given the differences among the U.S. regulatory system for medical devices and that of other countries, certain information presented in this memorandum may not be readily transferrable to other jurisdictions with different legal and regulatory compositions. Further, because of the unique context surrounding HIV laws in the United States -- including variable state and local laws regarding criminalization, confidentiality, and treatment -- the arguments in support of HIV self-testing may not be directly applicable to other countries. We have prepared this memorandum with these limitations in mind, however we nevertheless believe that the discussion of HIV self-testing within the United States provides helpful context for many of the legal and human rights issues implicated by SAT’s efforts. A table summarising the applicable laws on each of the questions and issues SAT has highlighted is provided in section 7 (Further Information).
- 1.3 This memorandum first provides background on how HIV tests are approved for commercial distribution in the United States, and then discusses the policy arguments for and against self-testing raised in the debate over approval in the United States. Furthermore, the memorandum discusses the first self-testing option available in the United States, which required mailing a specimen to a qualified laboratory to receive results, as well as the first rapid at-home test approved for use. Finally, this memorandum concludes with thoughts on how lessons from the U.S. experience with HIV self-testing can be applied in other countries.

2. Background on U.S. regulation of HIV self-testing

- 2.1 In the United States, tests that are used to determine whether an individual is infected with HIV are regulated by the Food and Drug Administration (the “FDA” or “agency”) under authority provided to the agency by legislation¹ enacted by the United States Congress. The FDA regulates the commercial distribution of numerous types of products including drugs, medical devices, biological products, dietary supplements, food, cosmetics, and tobacco products. Most HIV tests are considered “medical devices” because they are in vitro diagnostic instruments intended for the use in the diagnosis of disease,² see Federal Food, Drug, and Cosmetic Act § 201(h), and are regulated by the FDA’s Center for Biologics Evaluation and Research (“CBER”) under the FDA’s medical device authorities.³
- 2.2 HIV tests for professional and in-home use generally require premarket approval (“PMA”) prior to marketing, which is the process of scientific and regulatory review through which the FDA evaluates the safety and effectiveness of a medical device. This process requires the submission of a premarket approval application

¹ The relevant legislation is the Federal Food, Drug, and Cosmetic Act, which is routinely amended by legislation affecting the FDA’s authority to regulate drugs and devices. Broadly speaking, Congress provides wide latitude to the FDA to regulate these products, and the FDA regulates these tests as medical devices through its Center for Biologics Evaluation and Research.

² FDA has not issued a regulation defining and classifying HIV tests (including HIV STs). Consequently, HIV tests are by default regulated as Class III medical devices. HIV tests, including HIV STs, are generally categorized as “in vitro diagnostic devices,” which are defined in FDA regulations as “those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae . . . intended for use in the collection, preparation, and examination of specimens taken from the human body”). 21 C.F.R. § 809.3

³ In vitro tests for HIV that are recommended for blood donor screening and related blood bank practices are licensed as biologics, whereas in vitro tests for HIV that are not performed in relation to blood bank practices (e.g., quantitative HIV assays and diagnostic tests that evaluate specimens other than blood) are regulated by CBER as medical devices. See FDA, Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2 (December 1999).

to the FDA, and approval of a PMA application is based on a determination by the FDA that the application contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use. Bringing a medical device to market through the PMA pathway can be a very lengthy process, and applicants typically conduct extensive clinical studies to support the approval of their products.

- 2.3 In the U.S., there are four general categories of tests that can be used to test for HIV infection: (i) laboratory assays conducted by trained professionals, (ii) rapid HIV tests conducted in healthcare settings, (iii) mail-in tests, and (iv) in-home tests. HIV ST can be defined as testing in which the individual collects his or her own sample.⁴ In most cases, the diagnosis of HIV infection is conducted primarily through the use of laboratory-based assays or a rapid HIV test performed by a healthcare professional (“HCP”) in a healthcare setting.⁵ For individuals who wish to test anonymously, two categories of home-based testing options are also available. Mail-in tests allow a user to collect a dried blood specimen using an over-the-counter home specimen collection system. This specimen is then mailed to a laboratory for testing by a trained professional, and results are subsequently provided to the user via telephone. See *infra*, Section IV, Home Access HIV-1 Testing. In addition to mail-in testing, the FDA recently approved the OraQuick In-Home HIV Test (“In-Home Test”) -- the first entirely home-based test that individuals can use to receive a nearly immediate determination of HIV infection. See *infra*, Section V, OraQuick In-Home HIV Test. In its approval letter, FDA described OraQuick as “a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in human oral fluid specimens” intended for over-the-counter “consumer use as an aid in the diagnosis of infection with HIV-1 and HIV-2.” Unlike the mail-in tests, testing with OraQuick requires a user to be responsible for all aspects of the testing process, including administration of the test and interpretation of the results. Counselors are available to speak with individuals testing with the OraQuick product, however individuals still receive their results independently. It requires an affirmative step on the part of a self-testing individual to be put in touch with such a counselor.
- 2.4 Finally, as noted above, there are a number of laws related to home testing that are not addressed in this memorandum due to the uniqueness of the U.S. system. Privacy protections are an important consideration in any discussion of at home testing. Improper disclosure of HIV status can have many serious consequences because of the misperceptions, stigma, and discrimination surrounding HIV, including violence, social ostracism, and denial of employment. The United States has robust privacy laws and confidentiality guarantees for health information, including federal standards to protect the privacy and security of medical records, and also anti-discrimination laws that govern the use of such information when disclosed. Notably, however, power in the United States is shared between the federal and state governments, and local jurisdictions within the states also may have regulations governing issues related to HIV. Some laws related to the rights and obligations of disclosure of HIV-status are state-based and therefore may vary widely. Accordingly, it is difficult to draw conclusions or formulate specific recommendations based on the U.S. experience that will be relevant to the legal environment in Southern Africa. Similarly, it is difficult to draw generalities about criminal issues related to HIV from the perspective of the United States (e.g., those criminalizing the transmission or exposure to HIV) because these largely are state laws and vary from state to state. Indeed, not even all of the states have laws that specifically criminalize knowingly exposing another person to HIV. Due to these idiosyncrasies, we have limited our analysis and research in this memorandum to the broad legal and policy issues surrounding the implementation of HIV self-testing within the United States. For a high level summary of the applicable laws on each of the questions and issues SAT has highlighted please refer to the table provided in section 7.

3. Public policy arguments for and against self-testing in the United States

- 3.1 Approval of the OraQuick In-Home Test in the U.S. was the culmination of a debate regarding home HIV collection and testing kits that spanned more than two decades, with fervent arguments made on both sides. Traditional testing methods unquestionably fail to reach a substantial number of infected persons. In certain cases, the shortcomings of traditional, provider-based testing prevent early detection, which generally permits greater treatment success.⁶
- 3.2 Self-testing advocates argue that given the importance of early treatment and knowledge in mitigating the spread of HIV, any tool that can facilitate awareness of HIV status should be implemented. Moreover, people with HIV may fear social isolation and employment discrimination should their status be discovered, and at-home testing provides a discreet and convenient method of determining an individual’s HIV status. As a result, self-testing can minimize some of the barriers of stigma and inconvenience associated with testing in professional settings and may improve testing uptake.⁷ Increased rates of testing, moreover, may reduce HIV/AIDS-related stigma by normalizing HIV testing and perhaps even positive diagnoses.⁸
- 3.3 Further, rapid, at-home tests like OraQuick may facilitate linkage to care better than traditional testing methods. Specifically, because some traditional testing can take up to two weeks, certain individuals fail

4 See Sue Napierala Mavedzenge, Rachel Baggaley, and Elizabeth L. Corbett, *A Review of Self-Testing for HIV: Research and Policy Priorities in a New Era of HIV Prevention*, 57:1 CLIN. INFECT. DIS. 126 (July, 2013).

5 If a patient tests positive through one of these assays, a second test is conducted to confirm the results.

6 Sheldon Campbell and Roger Klein, *Home Testing to Detect Human Immunodeficiency Virus: Boon or Bane*, 44:10 J. CLIN. MICROBIO. 3473, 3473 (2006).

7 E.g., A. David Paltiel and Rochelle P. Walensky, *Home HIV Testing: Good News but Not a Game Changer*, *Annals of Internal Med.* 744, 745 (2012).

8 Janne Krause et al., *Acceptability of HIV Self-Testing: A Systematic Literature Review*, 13 BMC Pub. Health 735, 1 (2013).

to return to receive their results and thus are lost to follow-up care or counseling.⁹ And because at-home testing permits individuals to deal with the testing and results on their own time, proponents assert that it may actually decrease psychological distress compared to testing in the professional setting.¹⁰

- 3.4 In contrast, opponents have argued that the purported benefits of self-testing in terms of detecting cases and reducing transmission are overstated and unrealistic. In part, these arguments are premised on the idea that self-testing options would “attract a predominantly affluent clientele composed of persons at low risk for infection (the ‘worried well’ and new sexual partners), persons with very recent (and therefore undetectable high-risk exposures,¹¹ and persons with known HIV infection seeking to monitor their therapy or to pursue a misperception that treatment has reversed their seropositivity.”¹² Commentators also have criticized the practical benefits of at-home tests given that positive results require confirmation in the clinical setting.¹³
- 3.5 Other concerns commonly raised are related to accuracy, error, and misuse.¹⁴ The issue of false negatives is particularly significant with OraQuick, which generally cannot detect infection within the first ninety days of exposure. On this point, moreover, it bears mention that people generally are most infectious in the early weeks after infection. Further, there was concern that testers would misinterpret their results as final diagnoses and fail to seek follow-up testing or care.¹⁵ There were also concerns that positive results might increase suicides or could be misused to persecute HIV-positive individuals.¹⁶ Additionally, critics questioned the ability of lay people to conduct self-testing accurately.
- 3.6 Critics further have emphasized that testing cannot itself reduce the incidence of HIV or improve access to treatment. Testing in the professional setting generally provides a more direct link to counseling support and care, whereas disclosure of at-home test results and utilization of counseling services and care depend on the individual’s willingness to take action. Further, willingness aside, some individuals may have difficulty understanding and accessing information and services, particularly persons with limited means and education.¹⁷

4. First FDA-approved self-testing option: home access HIV-1 testing

4.1 Background

- 4.1.1 The Home Access Express HIV-1 Test System (“Home Access Test”), which is sold in the United States under the trade names Home Access® and Home Access® Express and manufactured by Home Access Health Corporation, was the first FDA-approved home testing option in the United States, approved on July 22, 1996. The product is approved for the purpose of anonymous HIV-1 testing for self-use by adults (defined as eighteen years or older). Although the test requires a blood sample, it is designed for use by individuals who have no training or experience in drawing blood specimens. The FDA approved the Home Access Test to provide education about HIV infection and risk reduction and to offer counseling, medical/psychosocial referrals, and assistance in partner notification. As indicated in the product’s name, the Home Access Test only indicates the presence of the HIV-1 strain of the virus; in contrast, the OraQuick In-Home Test, discussed below, can identify the existence of HIV-1 and HIV-2.

9 Alexi A. Wright and Ingrid T. Katz, Home Testing for HIV, 354:5 N. Eng. J. Med. 437, 439 (2006).

10 Carrie Arnold, At-Home HIV Test Poses Dilemmas and Opportunities, 380 World Report 1045, 1046 (2012).

11 The test detects a person’s immune system’s response to the virus. People typically develop a detectable response within six weeks of infection; most people will have developed a detectable within three months.

12 E.g., Paltiel, *supra* note 7, at 744.

13 E.g., *id.*

14 Campbell, *supra* note 6, at 3475.

15 Wright, *supra* note 9, at 439.

16 Roger Parloff, “The Quiet Scandal of the HIV Home Test Kit: Did the FDA’s Former Ban on Home Testing Kits Result in Thousands of Avoidable Infections,” CNNMoney (July 9, 2012).

17 Krause, *supra* note 8, at 7.

4.2 Use of the home access HIV tests

- 4.2.1 In order to use Home Access, individuals collect a blood specimen, which is then shipped to a qualified testing laboratory. The first step in the process is for the individual to call a toll-free number to register the unique 11-digit number provided in the kit. Following that point, the individual takes a blood sample and ships it to a Home Access testing center. The product comes with a “Directional Insert” that explains the process for collecting a blood sample. In general, the procedure requires an individual to draw a small amount of blood from a finger, and the Home Access Test and Home Access Express kits come with all the equipment necessary to draw the sample. Clinical tests have demonstrated that 98% of Home Access product users collect blood samples as effectively as phlebotomists, thus effectively eliminating concerns about specimen collection.¹⁸ Results of the Home Access Express test are ready in three business days, and the results of the regular Home Access test are ready in seven business days.
- 4.2.2 Test results from the Home Access products are extremely reliable. Because blood is used (rather than saliva, as with the OraQuick test), the sensitivity of the Home Access tests is effectively 100% (i.e., in clinical studies, the Home Access testing methods identified HIV-positive persons as positive in all cases).¹⁹ Consequently, the FDA has approved the product for marketing as having “99.9%” accuracy. In addition, the product packaging indicates that it is as “Reliable as Tests Used By Doctors and Hospitals.” In comparison to the OraQuick In-Home Test, discussed further below, the 99.9% accuracy rate runs across individuals who are determined to be both HIV positive and negative. On the other hand, while the OraQuick In-Home Test determines HIV negativity to a degree of 99.9%, HIV positivity is determined only to a 91.7% degree of accuracy.

4.3 Patient notification

- 4.3.1 It is notable from a policy perspective that the makers of the Home Access Test “reserve the right to defer giving test results to clients who are likely to harm themselves or others after they obtain their results.”²⁰ Although the packaging does not indicate how Home Access personnel may reach this conclusion, this warning nevertheless reflects one of the central concerns with HIV home testing in general, i.e., that certain individuals may not be equipped to deal with an HIV positive diagnosis.
- 4.3.2 To ensure results are conveyed in an appropriate fashion, with sensitivity to patient reaction, the Home Access Test results are classified into three categories: (1) negative; (2) indeterminate; and (3) positive. Many individuals who are determined to be HIV negative will receive their results from an automated system established by Home Access Health Corporation; these individuals will, upon request, have the option of speaking with a counselor. All individuals with indeterminate or positive results will receive results directly from live counselors. Individuals testing positive may speak with counselors 6 times over a 12-month period after their results become available.
- 4.3.3 In order to address concerns with patient reaction, counselors who deliver positive results are charged with assessing the coping skills, availability of personal support networks, and ability to inform sexual/needle-sharing partners. Information can be provided by the counselors to assist the individual with informing others about the positive test results, and, if requested, counselors will refer individuals to their local public health services. Clients with positive results are also referred to physicians or clinics within their geographic location, as well as a referral to the National AIDS Hotline and other psychosocial services if they want.

4.4 Policy and practical considerations

- 4.4.1 A major benefit to a mail-in self-testing option that relies on a blood sample, such as the Home Access Test, is that an individual's specimen can be tested in a qualified laboratory, and the efficacy of the testing comes with a higher degree of reliability and accuracy. In addition, individuals who test positive receive their results from a counselor who is trained to convey that news with sensitivity and can immediately provide information for the individual to access other healthcare and psychosocial services.

¹⁸ Home Access HIV-1 Test System Summary of Safety and Effectiveness, available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm091849.pdf>. Blood samples are tested according to Organon Teknika Corporation Vironostika HIV-1 enzyme immunoassay (“EIA”) licensed protocol or the Genetic Systems LAV EIA HIV-1 EIA, at the direction of the Home Access Health Corporation. The Waldheim Pharmazeutika Fluorognost Immunofluorescent HIV-1 Antibody (“IFA”) test is performed on all repeatedly EIA reactive blood spot samples.

¹⁹ Id. at 13.

²⁰ Home Access FDA Labeling available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/UCM091852.pdf>.

- 4.4.2 On the other hand, testing with a mail-in option like the Home Access Test requires a significant infrastructure to operate. Not only does this system rely upon the use of qualified testing laboratories and an effective mailing system, but an important element of the Home Access Test is the ability of the manufacturer to connect individuals with positive (or indeterminate) results with counselors. A mail-in option also involves a necessary delay in the receipt of results, which may cause anxiety or frustration for the impacted individual. In contrast, a rapid, complete self-testing option permits individuals with the ability to test at home, in complete confidence, and receive immediate results. As a practical policy consideration, counseling should always be made available to individuals who are testing on their own, but with the OraQuick product, individuals merely have the option to call in to receive counseling, which lessens the operational burdens involved.

5. Approval of OraQuick in-home HIV self-test

5.1 Background

- 5.1.1 As discussed above, the FDA approved the OraQuick In-Home Test in 2012. The agency has been criticized for not approving rapid at-home testing sooner -- the FDA first received a marketing request for a rapid at-home test in 1988.²¹ The agency deliberated on that request for approximately two years before deciding to restrict HIV testing to healthcare professionals.²² Over time, the agency's position shifted. As discussed above, the agency approved home-collection kits for HIV testing in 1996.²³ In 2005 and 2006, the agency held public hearings on the approval of the OraQuick In-Home Test, considering testimony from a diverse group of interested parties, including "physicians, evangelists, gay activists, venture capitalists, and public health officials."²⁴ The agency considered the legal performance requirements for home tests against the backdrop of the OraQuick In-Home Test's potential public health impact.

5.2 Use of OraQuick

- 5.2.1 OraQuick is manufactured by OraSure Technologies, Inc. The OraQuick In-Home HIV Test is based on the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test ("OraQuick Advance Test"), which is a lab-based professional HIV test that was first approved for marketing in 2003. The OraQuick In-Home HIV Test has the same design and is manufactured through the same process as the OraQuick ADVANCE Test. The only differences between the two products are in the packaging and labeling.
- 5.2.2 The OraQuick In-Home HIV Test is a single-use, qualitative immunoassay that is approved for the detection of antibodies to HIV-1 and HIV-2 in human oral fluid samples only. The test is available for purchase without a prescription online as well as at several commercial retail stores that are available throughout the U.S. The test is only approved for use in individuals 17 and older, with the barcode used to advise store clerks on the age restriction at the point of purchase.²⁵ When using the OraQuick In-Home Test, the user is responsible for all aspects of testing including collection of the specimen, administration of the test, and interpretation of the results. The In-Home Test is not intended for conclusive determination of HIV status. Rather, as set forth in product labeling, the In-Home Test is intended for consumer use "as an aid in the diagnosis of infection with HIV-1 and HIV-2" (emphasis added). Accordingly, the product labeling includes several statements advising users that confirmatory testing is needed (e.g., "A positive result with this test does not mean that you are definitely infected with HIV, but rather that additional testing should be done in a medical setting," and "A positive result means that you may have HIV. A doctor, clinic or healthcare professional must confirm your OraQuick® InHome HIV Test result.>").
- 5.2.3 To obtain a result using the OraQuick In-Home HIV Test, the user swabs his/her upper and lower gums to collect an oral fluid specimen onto a test stick. The user then places the test stick inside a test tube containing a developer solution, after which the user must wait 20 to 40 minutes before reading the results. If the specimen contains antibodies that react with HIV antigens, a reddish purple line appears in the device's "test zone" qualitatively indicating the presence of antibodies to HIV-1 and/or 2 in the specimen. In addition to the line in the test zone, if the test is functioning properly, a reddish-purple "control" line will also appear in the test's "control zone." If no antibodies to HIV-1 or HIV-2 are present in the specimen, only the control line is visible and the test should be interpreted as negative. By contrast, if antibodies to HIV-1 or HIV-2 are present in the specimen, two distinct lines appear in the test device window.

²¹ In 1988, the FDA declined to accept an application for a rapid home blood test for HIV. Parloff, *supra* note 16.

²² Wright, *supra* note 9, at 438. The FDA was sued over the decision.

²³ *Id.*

²⁴ *Id.* at 437.

²⁵ Berman, Shira. "At-Home Rapid HIV Testing: An Interview with FDA," *Medscape* (August 1, 2012) (Interview with Elliot Cowan, Chief of the Product Review Branch in the Division of Emerging and Transfusion Transmitted Disease at CBER).

A. CLINICAL STUDIES AND RISK-BENEFIT ANALYSIS

- 5.2.4 FDA's approval of the OraQuick In-Home HIV Test was predicated in part on the results of three categories of clinical studies: Phase I Studies to establish the performance of the test in the hands of trained users and the inherent sensitivity and specificity of the test, Phase II Studies to establish the performance of the test in the hands of untrained users under observation, and a Phase III Study to establish the performance of the test system as a whole in the hands of untrained users in the actual intended use setting (at home). As part of the Phase II Studies, OraSure conducted a Quantitative Label Comprehension Study to assess the ability of users to correctly comprehend key messages from the packaging and labeling, including understanding of key warnings, proper test procedures, and test result interpretation. All but one of the observed comprehension scores in the study were >80% with the majority being >90%.²⁶ In addition to the Quantitative Label Comprehension Study, the Phase II Studies also included a Device Interpretation Study, which tested the ability of users to interpret pre-determined test results that were fabricated to represent a negative, positive, weak positive, or invalid test result. Although users did not perform as well as expected in the Device Interpretation Test, FDA nevertheless advised OraSure that it could proceed with the Phase III Study.
- 5.2.5 The Phase III Study, which was designed to have users self-test as if they purchased the product, was, among other things, intended to establish the sensitivity and specificity of the test when used in the home. The specificity of the test as assessed in this study was calculated to be 99.98%, with 1 of the 4,903 HIV-negative subjects reporting a false-positive (as compared to confirmatory testing). The sensitivity was calculated to be 91.67%, with 8 of 96 HIV-positive subjects recording a false negative. This sensitivity value was lower than a pre-specified minimum sensitivity of 95% recommended by FDA's Blood Products Advisory Committee and lower than the sensitivity seen with the OraQuick ADVANCE Test (which has the same design and technological characteristics as the In-Home Test).
- 5.2.6 Given the test's lower than recommended sensitivity, FDA decided to "conduct a formal risk-benefit assessment to look at the public health implications of a test performing at this particular level of sensitivity."²⁷ FDA developed a risk-benefit model based on the projected number and sub-populations of individuals that would use the OraQuick In-Home HIV Test who would not otherwise be tested for HIV. FDA's risk-benefit model also considered that the lower sensitivity of the self-test could result in increased rates of HIV transmission due to the increased number of false negatives as compared to professional-use tests. Through this risk analysis, FDA determined that there was a potential for the OraQuick In-Home HIV Test to inform an additional 44,000 individuals about their HIV status, and that this in turn was projected to avert about 4,000 new HIV transmissions in the first year of marketing the test. FDA explained in its Summary of Safety and Effectiveness that "these model outcomes indicate both an individual benefit (new diagnosis) and a net public health benefit (HIV transmissions averted)."
- 5.2.7 However, as noted in the Summary of Safety and Effectiveness, the risk-benefit model also showed an individual health risk in the form of false negatives among people who would not otherwise be tested, with the model projecting approximately 4,500 false negative results in the first year of use alone. Regardless, FDA concluded that although the sensitivity of the test fell below the pre-specified minimum level of 95%, the projected individual and public health benefits "indicate a favorable benefit/risk profile." The FDA explained that "the information provided in the PMA and the benefit-risk model developed by FDA indicate that the projected benefits of the OraQuick® In-Home HIV Test outweigh the risks of false positive and false negative test results," concluding that "the available data provide reasonable assurance that the OraQuick® In-Home HIV Test is safe and effective for its intended use and support approval of the OraQuick® In Home HIV Test." With its approval, the FDA stressed that OraQuick is not one-hundred percent effective and is not intended to replace professional, facility-based HIV testing. Rather, OraQuick is another means to facilitate finding out HIV status, particularly by persons who might not otherwise be tested.²⁸

²⁶ The one exception was for the key message "what to do next if you are negative" for which the comprehension score was lower (77.5%).

²⁷ Berman, Shira. "At-Home Rapid HIV Testing: An Interview with FDA," *Medscape* (August 1, 2012) (Interview with Elliot Cowan, Chief of the Product Review Branch in the Division of Emerging and Transfusion Transmitted Disease at CBER).

²⁸ See, e.g., Report on the First International Symposium on Self-Testing For HIV: The Legal, Ethical, Gender, Human Rights and Public Health Implications of HIV Self-Testing Scale-Up, WHO (Apr. 2013).

B. PRODUCT LABELING AND SUPPORTING INFRASTRUCTURE

- 5.2.8 During review of the OraQuick In-Home HIV Test, FDA recognized the importance of the product's labeling in mitigating the risks associated with use of the test. In particular, FDA's Blood Products Advisory Committee emphasized the importance of stressing how results should be understood by including the following instructions to users:
- A positive result with this test does not mean that you are definitely infected with HIV, but rather that additional testing should be done in a medical setting;
 - A negative result with this test does not mean that you are definitely not infected with HIV, particularly when exposure may have been within the previous three months; and
 - Retesting is recommended if you test negative and continue to engage in behavior that puts you at risk for HIV infection.
- 5.2.9 In addition to incorporating the above messages, the product labeling also includes numerous other warnings and precautions, including that:
- Using this test earlier than 3 months after a risk event may not produce an accurate result.
 - Reading test results earlier than 20 minutes or later than 40 minutes may yield erroneous results.
 - Persons with increased risk for HIV infection should not interpret a negative test to indicate that engaging in high-risk behavior is safe.
 - This test is not to be used by individuals under the age of 17.
- 5.2.10 Unlike with professional HIV tests, in-person pre- or post-testing counseling is not required with the OraQuick In-Home HIV Test. Rather, product labeling is used in lieu of live counseling, as included with each test kit are a pre-test informational booklet entitled "HIV, Testing & Me" and a post-test booklet entitled "What your results mean to You!" For those users who want live counseling, however, the option is available through a "support center." OraSure has put into place an OraQuick Consumer Support Center call-in center that is available 24 hours a day/7 days a week/365 days a year. The Center, which has bilingual capability in Spanish and English, is designed to provide consumers with basic HIV/AIDS information, assistance in how to correctly perform and interpret the test, and referrals for confirmatory-follow-up testing and HIV care. Although Consumer Support Center Calls are confidential, the Summary of Safety and Effectiveness states that the Consumer Support Center can collect the caller's ZIP code, gender, test results, and age group, as well as inferred emotional status and whether the caller is a repeat caller. Additional system-generated information that can be collected includes the date of the call, agent, language, time of the call, resolution, questions asked, topic, area code, and action taken. As a condition of approval, the FDA is requiring OraSure to conduct surveillance of the Consumer Support Center usage to collect, and report annually to FDA, information on the number of individuals reporting positive results, negative results, and unknown results, "as well as demographic information that does not breach caller confidentiality."²⁹

6. Conclusions

- 6.1 Although there are significant policy arguments on both sides of the debate, HIV self-testing with a product like OraQuick can provide a meaningful supplement to HIV testing generally. From a policy standpoint, strategic implementation of self-testing necessarily will require understanding the perspectives of healthcare providers, patients, and various community groups in each community being considered. The United States has seen arguments made both in favor and against self-testing for a significant period of time, and the FDA's approval of such a product ultimately reflects a carefully considered approach. As discussed above, numerous safeguards have been built into self-testing with OraQuick, including the availability of a counseling telephone line.
- 6.2 Practically, although testing in a healthcare facility or with a mail-in option like the Home Access product may include a greater degree of reliability, there is also a significant level of dependability with a product like OraQuick. Indeed, a complete self-testing option presents a significantly easier implementation framework, especially given the considerable infrastructure necessary to roll out a product like Home Access. Moreover, self-testing is discreet and may significantly reduce the likelihood of discrimination or stigma -- while at the same time informing individuals of their status. Self-testing with a product like OraQuick should generally not be seen as a replacement for the availability of comprehensive provider-based HIV testing, but the potential positive impact identified by regulators in the United States -- both through informing individuals of their HIV status and also by preventing new infections -- cannot be understated.

²⁹ FDA, Approval Letter: OraQuick In-Home Test (July 3, 2012), available at <http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm310592.htm>

7. Further information

7.1 The table below is designed to provide context for various questions surrounding the regulation and implementation of HIV self-testing. In particular, this chart indicates certain U.S. laws that are implicated in relation to the questions raised and provides some background context. Please note, many of these issues are addressed not at a federal level in the U.S. legal system, but instead are governed and regulated by the individual U.S. states. For these issues, the table provides only generalities.

Question	US Laws Implicated
Are HIV self-testing kits currently legal?	HIVST kits are regulated as medical devices under the Federal Food, Drug, and Cosmetic Act.
What legislation governs the distribution of HIVST kits?	Federal laws, including the Food, Drug, and Cosmetic Act, govern medical device distribution. Additionally, approximately 25 states have regulatory oversight programs for device distribution; regulations vary.
What rules/conditions exist concerning the distribution of HIVST kits or similar devices?	Federal and State laws apply (see above). The distribution of medical devices, including HIVST kits, is subject to pre-market approval from the Food and Drug Administration.
The human rights issues surrounding HIV	Nothing specific beyond what is reflected in State and Federal laws.
Does every person have a right to be tested?	There has been no express recognition of a Federal right to HIV-testing. Many local health departments, public health clinics, and physicians offer HIV testing. Some testing is free. Some states require the provision of HIV testing to patients within a particular age range (e.g., New York requires that hospitals and primary care providers offer HIV tests to all patients between the ages of 13 and 64) or a particular subset (e.g., California requires providers to offer to test pregnant women).
Can a person be compelled to make any disclosures concerning a positive diagnosis?	Federal and State laws govern the protection of individuals' rights not to disclose HIV status, and also mandate disclosure in certain circumstances (e.g., notification to sexual partners of possible exposure to HIV).
Can a person be forced to take a test?	Federal and State laws govern mandatory testing. Mandatory HIV testing includes blood and organ donors and military personnel and, in certain circumstances, persons accused of sexual crimes, newborns, and prison inmates. In certain cases, HIV testing may be offered as opt-out instead of opt-in. Opt-out testing means the test is done unless the patient explicitly refuses.
Can a parent be compelled to have their children tested for HIV?	Yes, minors can sometimes be tested against their parents' wishes. Many states authorize minors to make decisions about their own medical care, especially in the context of HIV testing.
What is the law regarding discrimination based on a person's diagnosis with HIV?	Federal and State laws govern discrimination issues. Notable Federal laws include the Federal Americans with Disabilities Act ("ADA"), which prohibits discrimination on the basis of disability. The U.S.'s highest court has held that HIV-infection is a disability under the ADA.
If A Kit Is Faulty/Gives An Inaccurate Diagnosis, what Is The Liability Of the Supplier, to:	State laws, including consumer protection and products liability laws, are implicated and payment is not an essential prerequisite to all liability. Additionally, in certain liability regimes third parties may have a right of action against suppliers.
The Patient:	
Third Parties:	
Is the answer different if a kit is supplied free of charge?	
Must a person consent to HIV testing?	State laws generally govern informed consent issues. The U.S. Centers for Disease Control and Prevention does not recommend separate written consent for HIV testing beyond general informed consent for medical care notifying the patient that an HIV test will be performed unless the patient declines. Currently, most states have laws consistent with CDC recommendations. See http://www.cdc.gov/hiv/policies/law/states/index.html ; http://www.hivlawandpolicy.org/sites/www.hivlawandpolicy.org/files/2011%20UCSF%20Quick%20Reference%20Guide%20on%20HIV%20Testing%20Laws.pdf
Does consent have to be in writing?	

What is the legal age to give consent?	Generally, State laws govern age of consent and range between 14 and 18 years of age. Note, however, that capacity to consent is not based on age alone, but an individual's ability to understand and appreciate the consequences of his/her decisions (often as adjudicated by a court of law or other state officials).
What powers do parents/guardians hold in relation to consent process?	All of the states have specific laws regarding minors consenting to HIV testing. Certain states, however, permit physicians to notify parents of their child's HIV test results.
What are the rules/norms concerning the provision of counselling to those with a positive diagnosis?	States have various laws regarding counselling. See http://www.cdc.gov/hiv/policies/law/states/index.html ; http://www.hivlawandpolicy.org/sites/www.hivlawandpolicy.org/files/2011%20UCSF%20Quick%20Reference%20Guide%20on%20HIV%20Testing%20Laws.pdf Counselling may be pre-test as well as post-test.
Are test results confidential?	The Health Insurance Portability and Accountability Act ("HIPAA") is designed, in pertinent part, to protect the privacy of patients' medical records and health information. HIV tests may be taken confidentially or anonymously. Confidential testing means that the individual's name is attached to the test results, anonymous testing means that the individual gets a unique identifier that allows him/her to access his/her test results. Testing sites report positive HIV-test results to state health departments for surveillance purposes. State health departments, in turn, report to the U.S. Centers for Disease Control and Prevention, the federal agency responsible for tracking national public health trends. See http://www.cdc.gov/hiv/policies/law/states/index.html ; http://www.hivlawandpolicy.org/sites/www.hivlawandpolicy.org/files/2011%20UCSF%20Quick%20Reference%20Guide%20on%20HIV%20Testing%20Laws.pdf Some states require name-based reporting of HIV-test results to public health agencies. Additionally, there are special rules for the disclosure of HIV-status of persons serving time in jails or prisons under the Federal occupational health and safety standards.
Does a person have to disclose their HIV status to their: <ul style="list-style-type: none"> • Partner • Employer • Insurance provider 	Many states mandate notification of sexual partners and needle-sharing partners of possible exposure to HIV, commonly called "partner notification" laws. Generally, an individual is under no legal obligation to disclose his/her HIV-status to his/her employer unless it affects his/her ability to perform the job. Under the ADA, prospective employers cannot make inquiries about a prospective employee's health or the existence of a disability, including HIV-status, prior to making a conditional job offer. Importantly, the ADA does not protect the confidentiality of voluntarily disclosed information, including information about HIV-status. Whether an insurance plan can ask if an individual has been tested for HIV depends on the type of insurance. For example, an individual policy insurer may ask information about an individual's HIV/AIDS status. If an insurer has the right to ask, individuals must provide truthful answers.
Is it a criminal offence to transmit/attempt to transmit HIV?	More than half the States criminalize transmission of HIV. See http://projects.propublica.org/tables/penalties Some States provide for sentencing enhancement for sexual offenses involving risk of exposure to HIV.



Southern African AIDS Trust

REPORT

REGIONAL

2014



REVIEW -ZAMBIA

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



ZAMBIA

ZAMBIA

CORPUS LEGAL PRACTITIONERS

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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 HIVST 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 manufacture 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 content. 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:
 - a) 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;
 - b) 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
 - c) 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.zamlil.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.zambialil.org/files/zm/legislation/act/2011/1/Anti-Gender Based_Violence_Act%5B1%5D.pdf

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

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

6 <http://www.zamlil.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.zambialil.org/files/zm/legislation/act/2006/9/cea2006284.pdf>

9 <http://www.zambialil.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>



Southern African AIDS Trust

REPORT

REGIONAL

2014



REVIEW - ZIMBABWE

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



ZIMBABWE

ZIMBABWE

GILL, GODLONTON & GERRANS

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LEGAL PRACTITIONERS

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1. Introduction/Background¹

- 1.1 Zimbabwe's history has resulted in the diverse range of sources and influences on its law. It is one of the few remaining Roman Dutch law jurisdictions in the world, along with South Africa and a number of other southern African countries. This means that the writings of the old Roman Dutch jurists are binding law in Zimbabwe. Zimbabwe is a common law system, which means that the decisions of Zimbabwe's higher courts also create binding law, according to the doctrine of precedent. Significant persuasive weight is placed upon the decisions made by higher courts in other Roman Dutch law jurisdictions (especially South Africa) as well as the English courts. The Zimbabwe Parliament passes legislation through Acts of Parliament and may also delegate its legislative power to certain authorities who may pass legislation through Statutory Instruments. A new Constitution of Zimbabwe was recently enacted by Parliament and signed into law in May 2013. The Constitution is the supreme law of Zimbabwe and any law inconsistent with it is invalid to the extent of the inconsistency.
- 1.2 There is no law in Zimbabwe specifically dealing with HIV self-testing (HIVST). Nevertheless, there are laws that have bearing upon the issue and other issues around HIV testing which will be discussed below.

2. Summary of advice

2.1 Legality of HIVST

HIVST is not illegal in Zimbabwe, but it seems that it is not allowed at present by the Ministry of Health, as a matter of policy. The Ministry is, however, currently conducting an investigation into the appropriateness of HIVST in the Zimbabwean context.

2.2 Distribution

The distribution of testing kits is not currently regulated by the Medicines Control Authority of Zimbabwe (MCAZ). The MCAZ is legally empowered to regulate testing kits but at present the scope of their regulation does not extend to testing kits.

2.3 Human rights

- 2.3.1 Right to testing: There is no specific right to HIV testing under Zimbabwean law. There is, however, a justiciable right to health care services in Zimbabwe's Constitution, which may be interpreted to include a right to HIV testing. The state must take reasonable measures to achieve the progressive realisation of the right within its available resources.
- 2.3.2 Disclosures: The right to privacy in the Constitution, which explicitly includes the right not to have a health condition disclosed, protects against the disclosure of people's HIV statuses. This right may only be limited by a law of general application and only to the extent that it is fair, reasonable, necessary and justifiable.
- 2.3.3 Compelled to be tested: A person accused of committing a sexual offence may be compelled to be tested. It is, however, untested whether the courts will consider this law a justifiable limitation of the constitutional right not to be subjected to the extraction or use of their bodily tissue, without informed consent. With regard to children, a child's parent's decisions regarding the medical treatment or testing of their children will generally be respected. However, when it is in the best interests of the child to be tested, this will override the parent's decision, and they may be compelled to have their child tested.
- 2.3.4 Discrimination: Employees have a specific right not to be discriminated on the basis of their HIV status. Outside the employment context, protection against discrimination on the basis of HIV status would be based on section 56(3) of the Constitution on the ground that discrimination on the basis of HIV status is an analogous ground that infringes the dignity of the complainant or on the ground that having an HIV-positive status constitutes a "disability" for the purposes of the section.

¹ L Madhuku *An Introduction to Zimbabwean Law* (2010).

2.4 Liability

Liability for harm caused by a defective HIVST kit may arise out of the law of delict and the law of contract. Liability under the law of delict may arise whether the product was distributed freely or sold. If all the elements of delict are established, liability may extend to third parties who suffer loss as a result of a faulty testing kit, and may in addition to patrimonial loss, include damages for pain and suffering, loss of amenities of life, shortened life expectancy and other forms of non-patrimonial loss. Under contract law, liability is limited to the contracting party and as a general rule there is no liability for consequential loss caused by a defective product. The two exceptions to the general rule are as follows: when the seller is the manufacturer of the defective product or is a merchant seller who publicly professes to have attributes of skill and expert knowledge in relation to the kind of goods sold. In these two circumstances the seller may be held liable for full consequential loss. In terms of the Consumer Contracts Act, a party to a consumer contract may only exclude liability insofar as it is reasonably necessary to protect their interests.

2.5 Consent

Informed consent is required before someone may be tested. Informed consent means that the person understands the test procedure and the implications of the test result. The requirements for this are set out in national policy. Written consent is not required. A youth is presumed to have capacity to consent to medical procedures from the age of 16 years. If the child is already pregnant, or otherwise deemed to be an emancipated minor, they may be considered competent to consent before the age of 16 years.

2.6 Counselling

Both pre- and post-test counselling is required by national policy.

2.7 Confidentiality

National policy, together with the constitutional right to privacy, dictates that the confidentiality of the results of an HIV test must be respected. However, the concept of “shared confidentiality” (i.e. sharing the results with one’s partner and care-givers) is recommended.

2.8 Disclosure

A duty to disclose one’s HIV status to one’s sexual partner arises from the crime of wilful transmission of HIV. There is no duty to disclose one’s HIV status to one’s employer or prospective employer. There is a duty to disclose material facts to an insurer. A person’s HIV-positive status is likely to be considered a material fact for certain types of insurance contracts.

2.9 Criminal implications of transmitting HIV

It is a criminal offence in Zimbabwe to deliberately or recklessly transmit HIV to another person without their prior informed consent. It is not a defence that an accused person was married to the complainant/victim at the time of the offence. A person convicted of this offence may be sentenced to up to twenty years’ imprisonment. Transmitting HIV during the commission of any sexual offence or the crime of trafficking in persons will result in a harsher sentence.

3. Is HIV self-testing legal and, if so, under what conditions?

- 3.1 HIV self-testing is not prohibited by Zimbabwean law. In practice, however, it has not been allowed by the Ministry of Health. The Research Department of Parliament suggested that this is primarily due to concerns over how self-testing would be accompanied by counselling and linkage to care. Nevertheless, the Ministry is presently in the process of investigating whether HIV self-testing should be allowed in Zimbabwe.
- 3.2 The Ministry's *National HIV Testing and Counselling Strategic Plan 2013-2015* states that one of the implementation priorities to achieve the Ministry's objective of expanding coverage of HIV testing and counselling (HTC) is to pilot an HIV self-testing programme. Self-testing is not defined by the *Strategic Plan* but a technical definition of self-testing is currently being formulated as part of the process of drafting new HTC policy guidelines for Zimbabwe. The *Strategic Plan* states that the Ministry of Health will engage its implementation partners (including the private sector), at every stage of the process – from exploration and investigation to implementation. The *Strategic Plan* indicates that there is political will behind the introduction of HIV self-testing kits to Zimbabwe. As there is no legal barrier to HIV self-testing, and it seems that government policy is already moving towards the roll out of self-testing kits in Zimbabwe, it should not take too long for HIV self-testing to be approved in practice.
- 3.3 According to the *Strategic Plan* the timeline for the roll out of HIV self-testing is as follows: a national consultative meeting was to be held in the 3rd quarter of 2013 to review lessons learnt from the home based HTC pilot; next, guidelines and standard operating procedures for other “novel models” of HTC, including self-testing, were to be developed in the 4th quarter of 2013; lastly, the *Strategic Plan* envisions the gradual and strategic roll out of HIV self-testing in Zimbabwe, beginning in the 1st quarter of 2014. At the time of writing I was not able to establish what stages of the *Strategic Plan* the Ministry had achieved.
- 3.4 With regard to the conditions upon which HIV self-testing might be allowed in Zimbabwe, the *Strategic Plan* gives a brief indication. The *Strategic Plan* states that “*the appropriateness of self-testing in the Zimbabwe context will be investigated and piloted, with particular attention to issues of quality of results, psycho-social support and linkage to services.*” From that it can be extrapolated that HIV self-testing will only be allowed if the self-testing kits are able to consistently produce accurate results and that the obvious challenge of how to ensure that someone who tests themselves without the supervision of a medical practitioner receives adequate counselling and other services is addressed to the satisfaction of the Ministry.

4. What legislation governs the distribution of HIVST kits & what rules/conditions exist concerning this distribution?

- 4.1 The Medicines Control Authority of Zimbabwe (MCAZ) is empowered by the Medicines and Allied Substances Control Act [*Chapter 15:03*] to regulate the distribution of medicines and medical devices in Zimbabwe. HIV self-testing kits would be regarded as a medical device and therefore the MCAZ is authorised by law to regulate their distribution. However, the MCAZ does not, at present, regulate any testing devices. The only medical devices that MCAZ regulate at present are condoms and gloves.
- 4.2 In terms of section 28 of the Medicines and Allied Substances Act, the Minister may declare any medicine (the definition of medicine is broad enough to include testing kits) or class of medicines to be a “specified medicine”. The Minister declared “diagnostic agents” to be specified medicines through Statutory Instrument 542 of 1981. The term diagnostic agents was further defined in the Medicines and Allied Substances Control (General) Regulations, 1991 as including serological, skin tests, blood grouping, radiocontrast media, reagent strips and tablets and other diagnostic agents. While it might seem that an HIV self-testing kit would be considered a diagnostic agent, the MCAZ has confirmed that it does not consider testing kits to be specified medicines, and therefore does not expect them to be registered.
- 4.3 If, however, at any point in the future the Minister does declare testing kits to be a specified medicine then the following, more rigorous, controls would apply. In terms of section 29, it is illegal to sell (the definition of “sell” includes free distribution) a specified medicine unless it is registered. In order to be registered, the MCAZ must consider the availability of the medicine to be “in the public interest”, be satisfied that it is of its safety, quality and therapeutic efficacy, and that the manufacturing premises, if in Zimbabwe, are satisfactory. Registered medicines must comply with certain labelling standards specified in section 36 of the Act. According to section 40 of the Act, it is illegal to advertise a registered medicine to members of the public – they may only be advertised in a medical journal or to medical professionals. However, according to the MCAZ, products may be advertised to the public if the advertisement is approved by the advertising committee.

¹ L. Madhuku *An Introduction to Zimbabwean Law* (2010).

5. What are the human rights issues surrounding HIVST?

- 5.1 Zimbabwe's new Constitution, which came fully into force August 2013, has a justiciable Declaration of Rights which enshrines a host of fundamental human rights in Zimbabwean law which were not previously protected by the country's domestic law. The Constitution places a duty on the State, as well as private persons, to respect, protect, promote and fulfill these constitutional rights. The Declaration of Rights has both "vertical" and "horizontal" application, that is to say that it applies to the State and to private persons, including juristic persons.
- 5.2 Due to the fact that the new Constitution came into force quite recently, there is limited jurisprudence on how the courts will interpret its provisions. However, some guidance as to how the courts should interpret the Declaration of Rights is given in the Constitution itself. Section 46 requires the courts to interpret the Declaration of Rights in order to give "full effect to the rights and freedoms" enshrined in it. Furthermore, the courts must take international law into account, and may take foreign law into account when interpreting the Declaration of Rights. It is probable that the courts will look to South African constitutional jurisprudence for guidance due to both the similarity of the legal systems in general as well as the similarity of the Constitutions of the two countries.

5.3 Does every person have a right to be tested?

- 5.3.1 The Zimbabwe National Guidelines on HIV Testing and Counselling (the HTC Guidelines) state that "it is every Zimbabwean's right to know his or her HIV status." This right has not yet been given explicit legal effect, but it could be said to be protected implicitly by a number of provisions of the Constitution of Zimbabwe.
- 5.3.2 The right to healthcare is enshrined in the new Constitution of Zimbabwe. Although the right does not expressly include a right to be tested for HIV, it includes some provisions from which such a right may be inferred. Section 76(1) of the Constitution states that "[e]very citizen and permanent resident of Zimbabwe has the right to have access to basic health-care services, including reproductive health-care services." The United Nation Population Fund (UNFPA) states that "access to prevention, treatment and care for sexually transmitted infections, including HIV" should be a priority concern for reproductive health services. HIV testing is key to the prevention of the spread of HIV infections as well as for giving HIV positive patients access to appropriate treatment. The provision is restricted to citizens and permanent residents of Zimbabwe.
- 5.3.3 Section 76(2) of the Constitution is also relevant. It provides that "Every person living with a chronic illness has the right to have access to basic healthcare services for the illness." HIV/AIDS is widely regarded as a chronic illness. Therefore, it seems clear that this provision includes people with HIV. An argument may be made that in order to vindicate this right people will need to be tested to establish whether or not they have a chronic illness (such as HIV), and therefore the right should include a right to be tested. These arguments remain untested in the courts, and no legislation has been passed in order to give effect to these rights as mandated by section 76(4) of the Constitution.
- 5.3.4 As is the case with the other socio-economic rights in the Declaration of Rights, the achievement of the right to health care is made subject to available resources. The state must take reasonable measures to achieve the progressive realisation of the right. How the courts will interpret this is yet to be seen.

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

- 5.4.1 As a general rule, no one may be compelled to disclose their HIV status. Section 57 of the Constitution states that everyone has a right to privacy. Subsection (d) of that section specifically states that the right to privacy includes the right not to have a "*health condition disclosed*".
- 5.4.2 However, section 302A(5)(i) of the Criminal Procedure and Evidence Act [Chapter 9:07] allows the HIV status of a person convicted of a sexual offence to be revealed after the conclusion of the trial for the purpose of sentencing. This does not require the convicted person's consent, and indeed his or her HIV status may have been obtained via a compelled test (discussed further at section 5.5. below). Furthermore, the current *HTC Guidelines*, which at the time of writing were undergoing review, state that if a client has failed to disclose their HIV status to their sexual partner after three documented counselling sessions post receiving a positive HIV diagnosis and the counsellor feels that their client's partner is at risk of infection, then the counsellor may disclose that person's status to their sexual partner. Both of these constitute significant interferences with the constitutional right to privacy, and so it is not clear whether they will withstand constitutional scrutiny.

- 5.4.3 In terms of section 86 of the Constitution, rights and freedoms listed in the Declaration of Rights, such as the right to privacy, may only be limited by a law of general application and only to the extent that it is fair, reasonable, necessary and justifiable in a democratic society based on openness, justice, human dignity, equality and freedom, taking into account all relevant factors. Factors relevant to forced disclosure which are listed in the non-exhaustive list of relevant factors include public safety, public order, public morality, and public health. Section 302(5)(i) may meet this standard since it is a law of general application and there are perhaps arguments that could be made for why it is fair, reasonable, necessary and justifiable. The provision of the *HTC Guidelines* however, fails at the first hurdle, since it is provided for by policy rather than by law. On this basis, the Ministry of Health is likely to remove this provision from the new guidelines which are currently being drafted in order to bring HTC policy into line with the Constitution.

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

Criminal law

- 5.5.1 Section 302A of the Criminal Procedure and Evidence Act [Chapter 9:07] allows for the forced testing of persons accused of committing a sexual offence for the purpose of sentencing if the accused person is subsequently convicted. Section 302A(2) provides that “... *when an accused person is first brought before a court for remand on a charge of committing a sexual offence, or at any later stage, the court shall direct that an appropriate sample or samples be taken from the accused person, at such place and subject to such conditions as the court may direct, for the purpose of ascertaining whether or not he or she is infected with HIV.*” Reasonably necessary force may be applied to the accused person in order to take the sample.
- 5.5.2 The above provision constitutes a grave invasion of the accused's right to privacy (outlined above at section 5.4) as well as their right to bodily integrity enshrined in section 52 of the Constitution which includes the right “*not to be subjected to ... the extraction or use of their bodily tissue, without their informed consent.*” As acknowledged above, section 86 does allow (most) constitutional rights to be limited by law if certain requirements are met. However, it is doubtful whether the provision meets the requirements of section 86 that such limitation should be “fair, reasonable, necessary and justifiable”. It may, therefore, be struck down as unconstitutional if it is challenged in the courts, but until such time, persons can be forced to take an HIV test in terms of section 302A of the Criminal Procedure and Evidence Act.

Labour law

- 5.5.3 There are better protections against forced testing in Zimbabwean labour law. Section 4(1) of the Labour (HIV and AIDS) Regulations states that “[n]o employer shall require, whether directly or indirectly, any person to undergo any form of testing for HIV as a precondition to the offer of employment.” The provision does not, however, prevent medical testing of persons for fitness for work. A concern has, however, been raised by the Research Department of Parliament that employers use the provision allowing them to test for fitness for work to indirectly test a prospective employee for HIV and then decide not to employ that person – concealing it by stating in broad terms that the prospective employee failed their medical.
- 5.5.4 Persons who are already in employment are protected by section 5 of the Regulations which ensure that “[i]t shall not be compulsory for any employee to undergo, directly or indirectly, any testing for HIV.”

Children

- 5.5.5 Under Zimbabwean common law parents have the right to make decisions regarding their children's medical treatment. However, section 76 of the Children's Act creates an exception to that rule. Section 76(1) states:

Where the consent of a parent or guardian is necessary for the performance of any dental, medical, surgical or other treatment upon a minor and the consent of the parent or guardian is refused or cannot be obtained within a period which is reasonable in the circumstances, application may be made to a magistrate of the province where the minor is or is resident for authority to perform the treatment.

- 5.5.6 Once the magistrate has given the parents an opportunity to make representations to him or her regarding their reasons for refusal, he or she may grant an order for the medical treatment to be administered, if he or she is satisfied that it is in the best interests of the child to do so. This is in line with the Constitution which states that the “*child's best interests are paramount in every matter concerning the child*” and that every child has the right to health care services.

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

- 5.6.1 Section 5 of the Labour Act [*Chapter 28:01*] specifically provides protection for employees against discrimination based on their HIV/AIDS status. Outside of the labour context, protection from discrimination based on HIV status would be based on section 56(3) of the Constitution of Zimbabwe which ensures everyone has a right against unfair discrimination, but does not specifically mention HIV status. The section is worded as follows:

Every person has the right not to be treated in an unfairly discriminatory manner on such grounds as their nationality, race, colour, tribe, place of birth, ethnic or social origin, language, class, religious belief, political affiliation, opinion, custom, culture, sex, gender, marital status, age, pregnancy, disability, or economic or social status, or whether they were born in or out of wedlock.

- 5.6.2 Section 56(5) states that discrimination on any of the grounds listed in sub-section 3 is presumed to be unfair. Although HIV status is not explicitly included among the listed grounds, it may fall under "disability" or "social status" or may be regarded as an analogous ground. The point has not been decided in Zimbabwean law, and so it is useful to look to neighbouring jurisdictions. In the case of *Hoffman v South African Airways* (2000) 11 BCLR 1211 (CC) the South African Constitutional Court had to interpret a very similar provision in the South African Constitution which also does not expressly cover HIV status. The Court chose not to decide whether being HIV positive constituted a "disability", and instead found that discrimination based on HIV status was unfair discrimination on the basis that it was an analogous ground which impaired the dignity of a person.

6. What is the liability, to the patient and/or third parties, of a supplier if a kit is faulty/gives an inaccurate diagnosis? Is the answer different if a kit is sold rather than supplied free of charge?

- 6.1 Product liability claims may be made under the law of delict or the law of contract. The law of delict will apply whether the HIVST kit is sold or distributed freely. While it is probably less likely that a contract would be created when the product is distributed freely, the absence of the doctrine of consideration in Zimbabwean law means that the law of contract also has the potential to apply in both circumstances. The Consumer Contracts Act [*Chapter 8:03*] will apply where there is a contract for the sale or supply of goods or services in which the seller or supplier is dealing in the course of business and the purchaser or user is not.

Product liability under delict

- 6.2 Liability in delict for defective goods is sometimes referred to as "manufacturer's liability" as such claims are usually brought against the manufacturer of a defective product. In principle, however, it could be brought against others in the supply chain if all the elements are established.
- 6.3 Product liability is an area of the law of delict that is still in its infancy in Zimbabwe. To some extent, the same is true of South Africa.² Nevertheless, the scope of liability for defective products can, to some extent, be worked out from first principles notwithstanding limited case law, as the courts have placed product liability in delict under the broad Aquilian action. Under the Aquilian action it is necessary to prove, on a balance of probabilities, that all of the five elements of the law of delict are met. The five elements of delict are as follows: (1) conduct (2) wrongfulness (3) fault (intention or negligence) (4) factual and legal causation (5) harm.
- 6.4 The requirement of *conduct* may be established by an act or an omission by the defendant. This means that it is possible for a defendant to be held liable for *failing to do* something. However, when the conduct concerns an omission, there are special rules which apply to determine whether or not the defendant should be held liable. There is a general rule that negligent omissions that cause harm are not wrongful. However, the courts have developed an unclosed list of recognized situations which lead to a legal duty being imposed upon the defendant to take positive action. One of these is creation of a dangerous situation. The duty is on-going so manufacturers owe a duty to warn of dangers first identified after the product was supplied as a result of new knowledge derived from research or experience in the market. The courts have the power to recognise new additional categories and so ultimately it is a matter for judicial discretion whether to impose liability for an omission.
- 6.5 It is now trite law in Zimbabwe that in order to succeed in a delictual claim the plaintiff must plead both wrongfulness and negligence. The requirement of *wrongfulness* plays two important roles in the Zimbabwean law. Firstly, it decides whether there is any liability at all for a particular type of conduct, and secondly, to restrict the ambit of liability where liability is recognised. Wrongfulness is established when a legal duty was owed by the defendant to the plaintiff to act without negligence.³ (It is similar to the English law requirement of "duty of care").

² Neethling, Potgieter & Visser *Law of Delict* (3rd ed) Butterworths: 1999 p 322.

³ *Border Timbers Ltd v Zimbabwe Revenue Authority* HH-13-09.

- 6.6 In most cases the requirement poses no problem because the law of delict lays down that it is always wrongful (i.e. there is a legal duty imposed upon the defendant) if the conduct is a positive act which intentionally or negligently causes physical harm to a person or property resulting in financial loss.⁴ For example, if a person becomes infected with HIV due to a decision taken on the basis of an inaccurate test result – such result being inaccurate due to negligent manufacturing (positive act) – and that person makes a claim against the manufacturer for medical expenses (patrimonial loss) incurred as a result of the infection (physical harm), then wrongfulness will be automatically established by law.
- 6.7 Manufacturers and (as applicable) suppliers owe a duty to take reasonable care in the design, manufacture and handling of products and in ensuring the provision of adequate warnings and instructions for use with the products they manufacture and/or supply. In relation to product information, care should be taken in considering what languages should be used as well as whether written warnings and labelling will be adequate in areas where literacy rates are low. In these circumstances, the supplier would have to discharge its duty of care via other reasonable means to ensure individuals who use the self-testing kits do so safely. There is no duty to warn of dangers that are obvious or a matter of common knowledge.
- 6.8 If, however, the harm was caused by an omission rather than a positive act, or if it was not physical harm, but rather psychological harm or purely financial loss, then the need to positively establish the requirement of wrongfulness becomes necessary. In exercising its judicial discretion the court will take into account reasonableness, policy and constitutional norms.⁵
- 6.9 The test for *negligence* is whether a reasonable person in the position of the defendant would have acted differently; and according to the courts the reasonable person would have acted differently if the unlawful causing of damage was reasonably foreseeable and preventable. Abnormal use of the product is generally not regarded as reasonably foreseeable. Otherwise the manufacturer (or other blameworthy distributor) will be liable to *anyone* who suffers damage on account of the defective product provided that it is reasonably foreseeable. If a court finds that it is reasonably foreseeable that third parties may make decisions based upon the results of the tests, and suffer harm if the basis for those decisions is false, then an organisations that distribute self-testing kits, as well as manufacturers, may be liable to anyone who uses the kits, as well as third parties who suffer harm, if the results are inaccurate. The labelling of the kits may, again, be important in this regard. If the label clearly states that a person should not rely solely on the result produced by the test, but should go for confirmatory testing, then that may absolve the distributor/manufacturer of the testing kits of responsibility for actions taken based upon the test result.
- 6.10 In order to establish *causation* the claimant must show both factual causation and legal causation. The traditional test for factual causation is the 'but-for test': the claimant must prove that, but for the defendant's negligence the claimant would not have sustained the injury. For instance, a third party who would have engaged in unsafe sex regardless of the outcome of his/her partner's test results could not prove causation. Legal causation ensures that the defendant is not liable for harm caused that is too remote. The test for legal causation is that of reasonable foreseeability or, put another way, whether it was within the range of ordinary human experience that the harm would result from the defendant's conduct. It is not necessary to show that the precise manner in which the harm occurred or its exact degree or extent were foreseeable. All that is necessary is that harm of the kind in general was foreseeable.
- 6.11 *Damages* in delict are compensatory i.e. they are awarded to put the injured party into the position that person would have been in if the wrongful act had not occurred. Damages may be awarded for both patrimonial loss and certain types of non-patrimonial loss. Patrimonial loss would include medical expenses incurred due to a false positive test result and psychiatric medical treatment. A false positive test result may also give rise to damages for nervous shock suffered as a result of the diagnosis. Generally, the courts will only allow damages for nervous shock if it constitutes a recognized psychiatric injury. However, in *Thebe v Mbewe t/a Checkpoint Laboratory Services* 2000 (1) ZLR 578 (S), the Supreme Court allowed damages to be claimed for the transitory shock of receiving false HIV-positive test result, even though no evidence was adduced that the plaintiff had needed any medical treatment or counselling. A false negative test result may give rise to damages if the results lead to a delay in receiving treatment which is detrimental to the individual's health or the user infects a third party, such as a breast-feeding child. Third parties who become infected with HIV due to inaccurate test results may be able to claim medical expenses both for HIV treatment for any psychiatric treatment, pain and suffering, loss of amenities of life, and shortened expectation of life. Liability may even extend as far as a close relation of such third party if that close relation suffers traumatic shock when they find out about the infection of the said third party or, for loss of support, if they are the legal dependents of a third party who dies. Pure economic losses which are not a consequence of physical injury are not generally recoverable.

Product liability under the law of contract

- 6.12 Product liability under contract law in Zimbabwe is still largely governed by Roman Dutch common law

⁴ G Feltoe *A Guide to the Zimbabwean Law of Delict*

⁵ *Border Timbers Ltd v Zimbabwe Revenue Authority* HH-13-09.

as there has been only limited legislative intervention. The Consumer Contracts Act does not address the question of liability for defective products. The Act provides for relief against unfair consumer contracts, including cancelling, varying, or enforcing the whole or parts of the contract and awarding compensation. Section 5(1) outlines six circumstances in which a contract will be regarded as unfair for the purposes of the Act, two of which are of particular importance for product liability. Section 5(1)(d) of the Act states that a contract will be deemed to be unfair “if the consumer contract excludes or limits the obligations or liabilities of a party to an extent that is not reasonably necessary to protect his interests” or, in terms of section 5(1)(e), “if the consumer contract is contrary to commonly accepted standards of fair dealing”. These clauses do not, however, have a very significant effect on the common law relating to product liability.

- 6.13 Roman Dutch law provides a form of strict liability (that is liability which is not dependent upon proving fault) of the seller for the sale of defective goods. The *Aedilian* actions known as the *actio redhibitoria* and the *actio quanti minoris* hold the seller strictly liable based simply on the presence of a defect in the product at the time of the sale and delivery to the purchaser. However, neither of the remedies allow damages for consequential loss suffered as a result of the defect. The *actio redhibitoria* allows the return of the article to the seller in exchange for the purchase price, and the *actio quanti minoris* entitles a reduction in the purchase price. Therefore, neither of these remedies have any relevance if the product is distributed freely, and even when the product is sold the purchase price of an HIV self-testing kit is likely to be negligible in comparison to consequential loss that a faulty testing kit could cause.
- 6.14 There are, however, certain limited circumstances in Roman Dutch law where the seller of a defective product will be held strictly liable for full consequential loss. According to the *Pothier* rule the seller will be held strictly liable for the full consequential loss caused by a defective product if he or she was either the manufacturer of the product, or a “merchant seller” who professes to have special knowledge of the product sold. In such circumstances the seller would be liable, whether or not they were aware of the defect. The application of the *Pothier* rule with regard to the “merchant seller” was restricted in South African Roman Dutch law by the *Kroonstad Westelike Boere Ko-op Vereeniging v Botha* 1964 3 SA 561 (A) case to instances where he or she publicly professes to have attributes of skill and expert knowledge in relation to the kind of goods sold. The Zimbabwean Supreme Court referred to *Kroonstad* with approval in the case of *Transport and Crane Hire (Pvt) Ltd v Hubert Davies & Co (Pvt) Ltd* 1991 (1) ZLR 190 (SC). However, *Kroonstad* has been criticised in South Africa for watering down the *Pothier* rule, and ultimately the enactment of South Africa’s Consumer Protection Act has placed strict liability for consequential loss caused by latent defects upon the manufacturer and importer and a presumption of fault against the supplier. As stated above, Zimbabwe’s Consumer Contract Act provides very limited protection to the consumer, and so the consumer would need to rely on the *Pothier* rule or some other implied warranty that the goods were not defective.
- 6.15 A party to a contract may exclude liability which would arise under the common law. However, as stated above, the Consumer Contracts Act provides that such exclusion of liability must be reasonably necessary to protect their interests. What this means has not yet been defined by the courts. Furthermore, under Zimbabwean common law, a party may not exclude liability for a fundamental breach. A fundamental breach is one that goes to the root or purpose of the contract.

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 There is, generally, no distinction in Zimbabwean law between written and verbal consent. Therefore, it is acceptable for only verbal consent to be obtained before carrying out an HIV test, so long as it is informed consent.
- 7.1.2 The National Policy on HIV/AIDS for Zimbabwe, 1999 states that informed consent needs to be obtained before testing for HIV. This is reiterated in the Zimbabwe National Guidelines on HIV Testing and counselling (the HTC Guidelines) and the Zimbabwe National Guidelines for HIV Testing and Counselling in Children (the HTC Guidelines for Children).⁶ The HTC Guidelines state that while informed consent may vary according to different settings, three crucial elements must always be present: “providing pre-test information on the purpose of testing, and on the treatment and support available once the result is known, ensuring understanding and respecting the individual’s autonomy.” The HTC Guidelines for Children further elaborate that the patient, or where appropriate the patient’s parents, should understand the benefits and potential difficulties associated with having access to information regarding their HIV status; an understanding of the HIV testing procedure; the implications of a positive test result on their life or on the life of their family; and on that basis make a decision whether or not to be tested.
- 7.1.3 Failure to obtain informed consent may give rise to delictual liability. In the South African case of *C v Minister of Correctional Services* 1996 (4) SA 292 (T) the court awarded delictual damages to a prisoner who been tested for HIV without informed consent. In that case the prisoner was aware that the test was for HIV and that he had a right to refuse to be tested, but the information given to the prisoner fell short of the requirements for informed consent. The court took into account that the Department of Correctional Services had itself adopted the concept of informed consent as a prerequisite for testing prisoners and had specified the requirements for it. Similarly in Zimbabwe, since informed consent has been adopted as the standard by numerous national policies, which also outline what is required for informed consent, it is likely that the courts will hold medical practitioners to that standard.

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 the Children’s Act [Chapter 5:06] and the *HTC Guidelines* and the *HTC Guidelines for Children*, the legal age of consent to HIV testing in Zimbabwe is 16 years. Therefore, by law, any child who is aged 16 years or above and is requesting HIV testing should be considered able to give full informed consent. The definition of a child in the Children’s Act, which defines a child as a person under the age of sixteen, is not consistent with the Constitution, which defines a child as any person under the age of 18 years. Nevertheless, it is unlikely that this will change the legal age of consent for HIV testing, as it is generally considered in the best interests of the child to allow them to be tested if they wish to do so.
- 7.2.2 The *HTC Guidelines for Children* state that consent of a parent/guardian is required before performing an HIV test on a child who is below 16 years of age. Children below 16 years of age who are already parents or pregnant should be considered “emancipated minors” who can give consent and should not be denied access to HIV testing services. The *Guidelines* provide that when a child has been sexually abused, an HIV test should be carried out as part of the standard of care for survivors of sexual abuse. This should be done as soon as possible after the incident, preferably not later than 72 hours. The *HTC Guidelines for Children* do not explicitly say that the parent/guardian’s consent is not needed in such circumstances, but this seems to be implied. The Parliamentary Portfolio Committee on Health and Child Welfare has made recommendations that the age of consent for HIV testing should be lowered in light of research which indicates that early sexual debut and sexual abuse of young children is prevalent in Zimbabwe.

⁶ Note that a process of reviewing, updating and harmonising the both of the HTC Guidelines is already underway. Therefore the information drawn from both of these Guidelines will become outdated when the new Guidelines are adopted.

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

Pre-test counselling

7.3.1 The guiding principle is that the counsellor should answer honestly all questions raised by the person who is to be tested, using appropriate language. In some cases, there may need to be several pre-test counselling sessions before the person reaches a decision whether or not to proceed with the HIV test. Areas to be covered in the pre-test counselling session include:

- Reasons for HIV testing;
- Basic facts about HIV and AIDS;
- Assessment of the person's risk of infection, need and readiness for HIV test;
- Advantages, limitations and implications of HIV test results;
- Discussing risk reduction;
- Disclosure of test results to the person and how this disclosure may be undertaken;
- Exploration of care and support system;
- Obtaining consent from the person to be tested for HIV.

Post-test counselling

7.3.2 Post-test counselling must be provided for both HIV positive and HIV negative persons. Major components of the post-test counselling session include:

- Preparing the person to cope with the HIV result;
- Reviewing their risk reduction plan;
- Discussing positive living, ongoing care and support system, including psychosocial support, and referral linkages;
- Discussing the disclosure of test results and partner referral.

Follow up counselling, care and support should also be provided to both HIV negative and HIV positive patients

Disclosure

7.3.3 The *HTC Guidelines* state that HIV test results should be disclosed in person only to the patient, unless the patient is a minor. The *HTC Guidelines for Children* refer to the distinction between partial disclosure and full disclosure. Partial disclosure does not use the term "HIV" or refer to the virus directly, while full disclosure does so. Full disclosure should not necessarily be done straight away. A number of sessions may be needed to complete the process of disclosure, especially with children.

7.4 Confidentiality of test results

7.4.1 As stated above, it is a constitutional right not to have one's HIV status disclosed without one's consent. According to the *National Policy on HIV/AIDS for Zimbabwe*, confidentiality regarding a person's HIV status should be respected. The *HTC Guidelines* state that confidentiality is one of the guiding principles for the provision of HIV testing.

Confidential record keeping

7.4.2 According to the *HTC Guidelines*, all medical records, including those with HIV-related information, must be managed in accordance with appropriate standards of confidentiality. Only persons with a direct role in the management of the patient should have access to these records.

Anonymity

7.4.3 Persons are not required to give their true name when having an HIV test. They may have the test conducted under a pseudonym. This provides some measure of confidentiality of test results. Service providers are still required to maintain the same standards of confidentiality, even when a pseudonym is used.

7.4.4 Where tests are conducted for the purposes of obtaining surveillance data, the data is collected through unlinked anonymous screening in selected sites among sentinel groups throughout the country. This ensures the confidentiality of the statuses of those who participate in the surveys.

Disclosure to third parties

- 7.4.5 As a general rule disclosure of HIV tests results should only be made to the patient themselves in person. Disclosure of the results to anyone else should only be done with the patient's consent, which should be documented.
- 7.4.6 All patients and clients should be encouraged to disclose their status to their sexual partners. On-going counselling should be provided to facilitate this process. However, as it has already been discussed at paragraph 5.4.2, the *HTC Guidelines* provide that where a client has failed to disclose their status to their sexual partner after three documented counselling sessions and the counsellor feels that their client's partner is at risk of infection, the counsellor can disclose the information to the partner.
- 7.4.7 The Public Health Act [*Chapter 15:09*] places a duty upon medical practitioners and principals of schools and orphanages to disclose medical information to the local authority relating to persons in their charge with certain infectious diseases. The "local authority" is defined broadly in the Act as a municipal council or town council, any local board, any rural district council, or any other body or authority. However, HIV/AIDS has not been declared an infectious disease, despite the Minister having the power to do so, and so the provisions do not, at present, apply to persons infected with HIV.

7.5 Duties of disclosure to partner/employer/insurer

Partner

- 7.5.1 The existence of the crime of deliberate transmission of HIV means that there is a duty on a person who is aware that they are HIV positive to disclose that information to their partner, or risk being prosecuted under that criminal offence. The wording of the criminal offence makes it clear that the duty applies even in the case where the two persons are married.

Employer

- 7.5.2 There is no duty to disclose one's HIV status to one's employer. Section 5(2) of the Labour (HIV and AIDS) Regulations, 1998 states that "*[n]o employer shall require any employee, and it shall not be compulsory for any employee, to disclose, in respect of any matter whatsoever in connection with his employment, his HIV status.*" Further protection of employee's right to non-disclosure is provided by section 5(3) which prohibits the disclosure of an employee's HIV status by any person who acquired the knowledge of the employee's HIV status in the course of their duties, unless it is with the written consent of the employee or required by another law.

Insurer

- 7.5.3 Section 83A of the Insurance Act [*Chapter 24:07*] states that there is a duty to disclose to an insurer every fact or circumstances that would materially affect the calculation of the risk insured or the decision whether or not to enter into, renew, vary or reinstate an insurance policy. Furthermore, the duty to disclose such a fact or circumstance exists whether or not the insured has been asked about it. A person's HIV-positive status would probably be considered a material fact to certain types of insurance, most notably health insurance and life insurance. However, the section also places a duty on the insurer to inform the insured, before entering into, renewing, varying or reinstating a policy, that they have a duty to disclose this information. If the insurer fails to do so, they shall not be entitled to avoid any liability under the policy concerned on the ground of non-disclosure of a material fact or circumstance, unless the non-disclosure was fraudulent

8. What are the criminal implications of transmitting - or being reckless as to transmission of - HIV?

- 8.1 Criminal prosecutions in Zimbabwe are brought by the National Prosecuting Authority. Much of Zimbabwe's criminal law has been codified in a single Act, the Criminal Law (Codification and Reform) Act [Chapter 9:23]. In terms of section 18(1) of that Act, all the essential elements of a crime must be proved beyond a reasonable doubt for a person to be convicted of that crime.

Criminality of transmitting HIV

- 8.2 The Criminal Law (Codification and Reform) Act makes it a criminal offence to deliberately or recklessly transmit HIV to another person without their prior informed consent. Section 79(1) of the Act provides as follows:

Any person who (a) knowing that he or she is infected with HIV; or (b) realising that there is a real risk or possibility that he or she is infected with HIV; intentionally does anything or permits the doing of anything which he or she knows will infect, or does anything which he or she realises involves a real risk or possibility of infecting another person with HIV, shall be guilty of deliberate transmission of HIV, whether or not he or she is married to that other person, and shall be liable to imprisonment for a period not exceeding twenty years.

- 8.3 According to the *National Policy on HIV/AIDS for Zimbabwe* this crime should not cover mother to child transmission. However, if an HIV positive mother knowingly refuses to allow the testing or treatment of her child, or intentionally disregards advice not to breast feed her child, the courts may find that she is guilty of the offence.
- 8.4 Section 51(4)(b) of the Magistrates Court Act [Chapter 7:10] grants regional magistrates the power to give a more onerous sentence in the case of the crime of deliberate transmission of HIV (up to twenty years) than their normal jurisdiction would allow.
- 8.5 There were no reported cases up to December 2012 of anyone being prosecuted for deliberately or recklessly transmitting HIV. However, there have been reports in the media of people being charged with the offence where the charge was subsequently dropped.⁷

Implications for sentencing

- 8.6 Transmitting HIV also has implications for the sentencing of a person convicted of certain other crimes. Section 80 of the Criminal Law (Codification and Reform) Act imposes a minimum ten year sentence for a person convicted of certain sexual offences if it is shown that they were infected with HIV at the time of the commission of the crime, whether or not the convicted person was aware of their infection. The only reported case up to December 2012 that dealt with this issue was the case of *S v Safiko* HH-31-05. In that case, the equivalent provision in from the Sexual Offences Act [Chapter 9:12] was not applied due to the fact that the HIV test was carried out later than 30 days after the offence meaning that no presumption could arise that he was infected with HIV at the time of the offence.
- 8.7 Section 3(3)(f) of the Presidential Powers (Temporary Measures) (Trafficking in Persons Act) Regulations, 2014 makes it an aggravating circumstance to the crime of trafficking in persons if the victim is infected with HIV as a result of or on the occasion of the crime of trafficking.

⁷ VOA Zimbabwe News 'Willful Transmission of HIV in Spotlight as Zimbabwe Lawmaker Prosecuted' (30/062011). Available at <http://www.voazimbabwe.com/content/zimbabwe-journalist-says-lawmaker-infected-her-with-hiv-124673269/1458775.html>.

9. Further information

9.1 We have no further information to add.

10. References

10.1 Legislation⁸

- 10.1.1 Children's Act [*Chapter 5:06*]
- 10.1.2 Constitution of Zimbabwe Amendment (No. 20) Act 1 of 2013.
- 10.1.3 Consumer Contracts Act [*Chapter 8:03*]
- 10.1.4 Criminal Law (Codification and Reform) Act [*Chapter 9:23*].
- 10.1.5 Criminal Procedure & Evidence Act [*Chapter 9:07*].
- 10.1.6 Labour Act [*Chapter 28:01*]
- 10.1.7 Magistrates Court Act [*Chapter 7:10*]
- 10.1.8 Medicines and Allied Substances Act [*Chapter 15:03*].
- 10.1.9 Public Health Act [*Chapter 15:09*].

10.2 Statutory Instruments

- 10.2.1 Labour (HIV and AIDS) Regulations, 1998.
- 10.2.2 Medicines and Allied Substances Control (General) Regulations, 1991.
- 10.2.3 Presidential Powers (Temporary Measures) (Trafficking in Persons Act) Regulations, 2014.
- 10.2.4 Statutory Instrument 542 of 1981.

10.3 Case Law

10.3.1 Zimbabwean cases

- 10.3.1.1 Thebe v Mbewe t/a Checkpoint Laboratory Services 2000 (1) ZLR 578 (S).
- 10.3.1.2 Border Timbers Ltd v Zimbabwe Revenue Authority HH-13-09.
- 10.3.1.3 Transport and Crane Hire (Pvt) Ltd v Hubert Davies & Co (Pvt) Ltd 1991 (1) ZLR 190 (SC).

10.3.2 South African cases

- 10.3.2.1 Kroonstad Westelike Boere Ko-op Vereeniging v Botha 1964 3 SA 561 (A).
- 10.3.2.2 C v Minister of Correctional Services 1996 (4) SA 292 (T).
- 10.3.2.3 Hoffman v South African Airways (2000) 11 BCLR 1211 (CC).

10.4 Government Documents

- 10.4.1 Zimbabwe National Guidelines on HIV Testing and Counselling, 2005.
- 10.4.2 Zimbabwe National Guidelines for HIV Testing and Counselling in Children, 2008.
- 10.4.3 National HIV Testing and Counselling Strategic Plan, 2013-2015.
- 10.4.4 Zimbabwe National HIV/AIDS Strategic Plan, 2011-2015.
- 10.4.5 National Policy on HIV/AIDS for Zimbabwe, 1999.

10.5 Other Documents

- 10.5.1 G Feltoe A Guide to the Zimbabwean Law of Delict (2001).
- 10.5.2 Neethling, Potgieter & Visser *Law of Delict* 3rd ed (1999).
- 10.5.3 L Madhuku An Introduction to Zimbabwean Law (2010).
- 10.5.4 D J McQuoid-Mason 'Common-Law Protection of the Consumer in South Africa'.
- 10.5.5 Snyman 'Products Liability in modern Roman Dutch Law'.
- 10.5.6 T Woker 'Why the need for consumer protection legislation? A look at some of the reasons behind the promulgation of the National Credit Act and the Consumer Protection Act'.

⁸ All Acts of Parliaments are available online from the website of the Parliament of Zimbabwe: <http://www.parlzim.gov.zw/>.

- 1.1.1 G Feltoe A Guide to the Zimbabwean Law of Delict (2001).
- 1.1.2 Neethling, Potgieter & Visser *Law of Delict* 3rd ed (1999).
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