MULTI-JURISDICTION REVIEW OF THE LEGAL ISSUES SURROUNDING THE DISTRIBUTION OF HIV SELF-TESTING KITS
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 summary findings of the multi-country reports.

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

This legal review report and the information it contains is provided for general informational purposes only. It has been prepared as a work of comparative legal review only and does not represent legal advice in respect of the laws of Botswana, Malawi, Mozambique, Tanzania, Zimbabwe, Zambia, South Africa, the United Kingdom, the United States of America and France. It does not purport to be complete or to apply to any particular factual or legal circumstances. It does not constitute, and must not be relied or acted upon as legal advice or create an attorney-client relationship with any person or entity. Neither Arnold & Porter (UK) LLP, Arnold & Porter (US) LLP, Corpus Legal Practitioners (Zambia), Dechert (France), Gill, Godlonton & Gerrans (Zimbabwe), Nexus Attorneys (Tanzania), Norton Rose Fulbright (South Africa), Pimenta, Dionisio e Associados (Mozambique), Rantao Kewagamang Attorneys (Botswana), Savjani & Co (Malawi), the Southern African Aids Trust, nor the Thomson Reuters Foundation accept responsibility for losses that may arise from reliance upon the information contained in this review note or any inaccuracies therein, including changes in the law since the review commenced in February 2014. Legal advice should be obtained from legal counsel qualified in the relevant jurisdiction(s) when dealing with specific circumstances. Neither the above mentioned legal firms nor any of the lawyers at these firms, the Southern African Aids Trust, nor the Thomson Reuters Foundation is holding itself, himself or herself out as being qualified to provide legal advice in respect of any jurisdiction as a result of his or her participation in or contributions to this legal review report.
MULTI-JURISDICTION REVIEW
OF THE LEGAL ISSUES SURROUNDING
THE DISTRIBUTION OF HIV SELF-TESTING KITS IN
BOTSWANA
ENGLAND & WALES
FRANCE
MALAWI
MOZAMBIQUE
SOUTH AFRICA
TANZANIA
UNITED STATES OF AMERICA
ZAMBIA
ZIMBABWE

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 (US) LLP      United States of America
- Corpus Legal Practitioners      Zambia
- Dechert           France
- Gill, Godlonton & Gerrans      Zimbabwe
- Nexus Attorneys      Tanzania
- Norton Rose            South Africa
- Pimenta, Dionisio 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 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.

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.
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</tr>
<tr>
<td>4. If a kit is faulty or gives an inaccurate diagnosis, what is the liability of the supplier?</td>
<td>-</td>
<td>-</td>
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<td>-</td>
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</tr>
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</table>

**4. SUMMARY OF COUNTRY REPORTS**
<table>
<thead>
<tr>
<th>Question</th>
<th>Botswana</th>
<th>Malawi</th>
<th>Mozambique</th>
<th>South Africa</th>
<th>Tanzania</th>
<th>Zambia</th>
<th>Zimbabwe</th>
<th>France</th>
<th>England</th>
<th>USA1</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) The Patient:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
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<tr>
<td>Tort/Delict</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Contract law</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Statutory consumer protection laws</td>
<td>✓66</td>
<td>✓56</td>
<td>✓34</td>
<td>✓26</td>
<td>✓16</td>
<td>✓29</td>
<td>✓45</td>
<td>✓35</td>
<td>✓46</td>
<td></td>
</tr>
<tr>
<td>(b) Is the supplier liable to third parties?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>N/A</td>
<td>Unlikely</td>
<td>Yes, but not under contract law</td>
<td>Yes</td>
<td>Yes, but not under contract law</td>
<td></td>
</tr>
<tr>
<td>(c) The answer different if a kit is supplied free of charge?</td>
<td>No16</td>
<td>No</td>
<td>Yes10</td>
<td>No</td>
<td>No</td>
<td>Yes31</td>
<td>No32</td>
<td>No</td>
<td>Yes35</td>
<td></td>
</tr>
<tr>
<td>Further issues concerning HIV</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Must a person consent to HIV testing?</td>
<td>Yes</td>
<td>Not specified14</td>
<td>Yes</td>
<td>Yes79</td>
<td>Yes76</td>
<td>No67</td>
<td>Yes11</td>
<td>Yes68</td>
<td>Yes12</td>
<td></td>
</tr>
<tr>
<td>(b) Does consent have to be in writing?</td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>(c) What is the legal age to give consent?</td>
<td>16 Parental consent required.</td>
<td>1315 Parental consent required.</td>
<td>12 Parental consent required.</td>
<td>18 written consent from parents/Guardian required.</td>
<td>16 Parent/guardian consent required.</td>
<td>18 Parents/guardian consent required.</td>
<td>16 Younger children can give consent if deemed competent.</td>
<td>14 - 18 years16</td>
<td>The rules vary by state16</td>
<td></td>
</tr>
<tr>
<td>(d) What powers do parents/guardians hold in relation to consent process?</td>
<td>Pre and post-test counselling is mandated, but the information to be provided is not specified.</td>
<td>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.</td>
<td>Pre and post-test counselling is a legal condition for the provision of testing in HIV testing centres.</td>
<td>Pre and post-test counselling is required for testing of children. Adults are offered counselling but may refuse.</td>
<td>Pre and post-test counselling is a legal condition for the provision of testing in HIV testing centres. Adults are offered counselling but may refuse.</td>
<td>Pre and post-test counselling is required during which the limits of reliability must be explained.</td>
<td>Pre-test counselling establishes informed consent. Post-test counselling discusses the stage of the disease, treatment, and partner notification.</td>
<td>The rules/norms vary by state16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(e) What are the rules/norms concerning the provision of counselling to those with a positive diagnosis?</td>
<td>Counselling is normal. Counselling should encourage, HIV-positive persons to notify their partners.</td>
<td>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.</td>
<td>Counselling is required for testing of children. Adults are offered counselling but may refuse.</td>
<td>Pre and post-test counselling is required for testing of children. Adults are offered counselling but may refuse.</td>
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<td>Pre-test counselling establishes informed consent. Post-test counselling discusses the stage of the disease, treatment, and partner notification.</td>
<td>The rules/norms vary by state16</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(f) Are test results confidential?</td>
<td>Yes</td>
<td>Yes26</td>
<td>Yes</td>
<td>Yes9</td>
<td>Yes9</td>
<td>Yes92</td>
<td>Yes93</td>
<td>Yes95</td>
<td>Yes91</td>
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10

SAT Regional
<table>
<thead>
<tr>
<th>Country</th>
<th>Question 1: Does a person have to disclose their HIV status to their:</th>
<th>Yes</th>
<th>No</th>
<th>State laws apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>Partner</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Malawi</td>
<td>Employer</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Mozambique</td>
<td>Insurance provider</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>France</td>
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<tr>
<td>USA</td>
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6. Is it a criminal offence to transmit/attempt to transmit HIV? Yes Yes Yes Yes

7. State laws apply: Yes Yes Yes Yes

8. Question 2: Does a person have to disclose their HIV status to their:

<table>
<thead>
<tr>
<th>Country</th>
<th>Question 2: Does a person have to disclose their HIV status to their:</th>
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<th>No</th>
<th>State laws apply</th>
</tr>
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<tr>
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<td>No</td>
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<td>No</td>
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<td>No</td>
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6. Is it a criminal offence to transmit/attempt to transmit HIV? Yes Yes Yes Yes

7. State laws apply: Yes Yes Yes Yes

8. Question 2: Does a person have to disclose their HIV status to their:
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 benchmarking exercise.

13. This is a general law relating to consumers. Malawi does not have legislation specific to medicines or medical devices.


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 himself/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 infection is suspected; (ii) in screening of pregnant women; (iii) 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.

37. Testing without consent make 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.
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.

When the person is accused of a sexual offence.

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 op-out instead of opt-in. Opt-out testing means the test is done unless the patient explicitly refuses.

If the parents are deemed to unreasonably withhold consent

Mandatory testing should only be done in the best interest of the child and without any form of coercion from the counselor.

A child may be tested against the wishes of its parents if it is in his/her best interest.

A child may be tested against the wishes of its parents if it is in his/her interest.

Yes, minors 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.

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.

Under section 20 of the Malawian 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.

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.

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.

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.

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.

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.

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.

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.

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.

Consumer Protection Act

The Mozambican Civil Code

The Consumer Defence Act

Consumer Protection Act

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.

Sale of Goods Act

Medicines and Allied Substances Act, Foods and Drugs Act and the Competition and Consumer Protection Act

Common law and Consumer Contracts Act


Consumer Protection Act 198

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.

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.

The claimant would need to establish a nexus for their loss/damage and the supplier’s negligence.

Liability will arise if the supplier undertook responsibility.

Only tort applies

Depending on the circumstances contract law may not apply.

Only the common law tort of negligence applies. Depending on the circumstances statutory liability under the Consumer Protection Act may apply.

The form of consent required is not specified.

The form of consent required is not specified, but most private clinics require written consent.

Consent is required unless a court orders otherwise.

Consent must be informed i.e. the persons agreed to the procedure based on full information.

Informed consent required.

Consent is required except where a court orders that a child be tested, contrary to the parent’s intentions.
ENDNOTES (CONT)


85 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.

86 16 is the legal age of majority but children aged 13 and over are entitled to access voluntary testing and counseling without the consent of a guardian or other adult.

87 A person is technically deemed a minor until 21 but minors between 16 and 21 can give consent.

88 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

89 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).

90 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.

91 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.

92 Constitutional right to privacy

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 the 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 he/she may or should be aware of, which may influence the insurance company’s assessment of the risk.

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107 Constitutional right to privacy

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109 The results of an HIV test shall be confidential and shall be released only to the person tested.

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SOUTHERN AFRICAN AIDS TRUST

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

What We Do
We strengthen systems to create resilient communities across southern Africa

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