



Southern African AIDS Trust

**REPORT**

**REGIONAL**

**2014**



**REVIEW – ENGLAND & WALES**

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



# FOREWARD

While the focus of much of the global community may be moving on from HIV and AIDS to other issues, it cannot yet be said to be “the end of AIDS” in Africa. HIV & AIDS will continue to impact communities and public health systems in eastern and southern Africa for decades to come and both morbidity and mortality in the region will be significantly increased as HIV & AIDS influences health issues such as TB, maternal mortality, and sexual and reproductive health more broadly.

One of the key critical success factors in fulfilling the UNAIDS and global goal of zero new infections, zero deaths and zero discrimination is people knowing their own HIV sero-status and having the ability to act on the knowledge. Yet in eastern and southern Africa, despite decades of investment in HIV testing and counselling, many people still do not know their status.

Across the region there remain wide variations in data regarding the proportion of the general population who have accessed HTC. Figures for 2011<sup>1</sup> show Botswana at over 60% (2011), Malawi at 34%, and Zambia 15%. **Presently less than half of all Africans know their HIV status, and only 25% received an HIV test in 2012<sup>1</sup>.** Uptake and access to HIV testing is lower among members of key population communities who, while facing a higher HIV burden, also face issues of stigma, discrimination and other barriers to access.

It is in this context that SAT believes in thinking out-of-the-box. After decades of investment more of the same is unlikely to be a game changer with regard to increasing the number of people empowered by knowledge of their own status to take action.

HIV self-testing may be just such an ‘out-of-the-box’ solution. Defined as, ‘when a test is collected, performed and interpreted in private by the individual who wants to know their HIV status’, self-testing, in combination with other new thinking on HTC opens new possibilities for reach and engagement.

To explore this possibility, SAT commissioned a multi-country legal review of national policies and legislation that frame and provide the context for thinking about HIV self-testing.

With the generous coordination from the Thomson Reuters Foundation, SAT worked with a strong team of international and Southern African legal firms to conduct a review of the laws relevant to HIV self-testing (HIVST) in their respective jurisdictions, namely Botswana, Malawi, Mozambique, South Africa, Tanzania, Zambia and Zimbabwe as well as France, the UK (England) and the USA. All work conducted by the firms (see below) was done on a pro bono basis as a contribution to global development.

The review sought to answer key contextual questions that would frame any pilot or projects that countries might choose to take up to increase numbers of the population who know their HIV status. Included were questions such as, “Is HIV self-testing legal and, if so, under what conditions?”, “What legislation governs the distribution of HIVST kits and what rules/conditions exist concerning this

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

distribution?” and “What are the human rights issues surrounding HIVST?” The review looked across SAT’s countries of operating but also went broader to explore the situation in the USA, France and the UK – all of which have now legalised self-testing after thorough national debates and scientific input.

In the last stages of the review SAT and the University of Witwatersrand Reproductive Health Institute hosted a Consultative Workshop in March 2014 with participants from governments, National AIDS Councils, key population groups, community organisations, WHO, medical experts and researchers. The think tank worked with the emerging review as well as with evidence from two very successful research/pilot sites in the SADC region and explored what the possibilities and practicalities of implementing self-testing might be. The think tank report may also be accessed on the SAT website above.

The issue of self-testing is not uncontroversial, and it has been known to raise strong feelings both for and against. The think tank was useful and hearing from the research sites de-bunked many of the myths about self-testing such as “it is incompatible with referring people into the health system”, or “people will not understand how to use it or how to interpret the results”. Innovators in a number of places, not least in the SADC region, have worked hard and designed and tested solutions and in some cases products to overcome these challenges.

HIV self-testing is not a magic bullet. In combination with other innovative thinking, however, it may hold the key to increasing reach of testing, opening new options for hard to reach communities, making life easier for serodiscordant couples and supporting both prevention and treatment.

We are pleased to present to you the HIVST Legal Report for England & Wales. This report is intended to inform SAT and all its strategic partners about the legal framework and human rights implications relevant to HIVST in England & Wales.

The summary consolidated findings for all the above mentioned countries as well as individual country reports are available at SAT on request as well as on the website, [www.satregional.org](http://www.satregional.org) .

It is our fervent hope that the findings will have a catalytic effect on dialogues on this subject and forge a way for HIV self-testing in England & Wales and across the region.

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

Jonathan Gunthorp



Executive Director - SAT

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

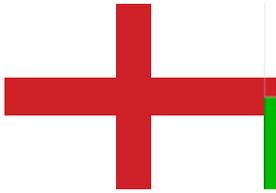
Last but not least, we would like to thank Thomson Reuters Foundation's global pro bono service, TrustLaw, who helped coordinate the project and brokered, free of charge, the relationships between SAT and the legal firms.

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REVIEW



# ENGLAND & WALES

**ENGLAND & WALES**

**ARNOLD & PORTER (UK) LLP**

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ARNOLD & PORTER LLP

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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.<sup>1</sup> 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.<sup>2</sup> Despite the ban on HIVST kits, in the past they could be acquired over the internet<sup>3</sup> 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 Foresight<sup>4</sup> report in 2006 on the future of detection, identification and monitoring systems for infectious diseases.<sup>5</sup> The report took into account an analysis on the development of mobile diagnostic devices and their potential for tackling infectious diseases including HIV.<sup>6</sup> 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.*<sup>7</sup>
- 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.<sup>8</sup>
- 3.6 In August 2013, the Department of Health released a statement on its plans for the modernisation of HIV rules.<sup>9</sup> 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 business<sup>10</sup>. 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 repealed<sup>11</sup>. Public Health England has issued answers to frequently asked

<sup>1</sup> Section 23 Health and Medicines Act 1988

<sup>2</sup> Regulations 2, 4 and 5 of HIV Testing Kits and Services Regulations 1992

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

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

<sup>5</sup> 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

<sup>6</sup> 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

<sup>7</sup> 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

<sup>8</sup> 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

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

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

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

questions on HIV testing and self-testing<sup>12</sup> 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 systems<sup>13</sup>. 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 guidelines<sup>14</sup>. The government expects this will change in 2014/15<sup>15</sup>.
- 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"<sup>16</sup>

## 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.<sup>17</sup> 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 set out

<sup>12</sup> 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](http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317141025695)

<sup>13</sup> 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](http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317141025695)

<sup>14</sup> 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>

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

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

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

in Annex I of the IVD Directive,<sup>18</sup> 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 body<sup>19</sup>). 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.<sup>20</sup>

### **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:

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

<sup>19</sup> 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.

<sup>20</sup> IVD Directive, Art 4(1)

- ensure that the device is easy to use by the intended lay user at all stages of the procedure, and
- 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.<sup>21</sup>

4.9 There are also specific requirements relating to the information supplied by the manufacturer with self testing kits.<sup>22</sup> 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.<sup>23</sup> The Common Technical Specifications which set out criteria for HIV testing kits were published in the Official Journal on 3 February 2009.<sup>24</sup> 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%.<sup>25</sup> 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.<sup>26</sup> 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).<sup>27</sup> 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.<sup>28</sup> 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.<sup>29</sup>

4.15 Once the manufacturer is in compliance, and has a certificate of compliance from a notified body, he may

<sup>21</sup> IVD Directive, Annex I, para.7

<sup>22</sup> IVD Directive, Annex I, para. 8.7(t).

<sup>23</sup> IVD Directive, Art 5(3)

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

<sup>25</sup> Commission Decision 2009/108/EC, paragraph 3.1.12

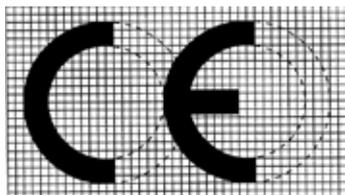
<sup>26</sup> IVD Directive, Art. 9, MD Regulations, Reg. 40, which cross-refers to the relevant Annexes in the IVD Directive

<sup>27</sup> MD Directive, Reg 40(3); IVD Directive, Art 9(2)

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

<sup>29</sup> 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.<sup>30</sup>



- 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 - MHRA<sup>31</sup>). 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.<sup>32</sup> 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.<sup>33</sup>

## 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-health<sup>34</sup>. 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 Rights<sup>35</sup> of the European Union (“the EU Charter”) was implemented into EU law to recognise formally the rights and freedoms of every individual in the EU<sup>36</sup>. It should be noted that the UK opted out of the Charter<sup>37</sup>. The EU Charter mirrors the ECHR in many respects such as the right to a private life<sup>38</sup> 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 to Member

<sup>30</sup> MD Regulations, Reg. 36 and IVD Directive, Art. 16(2)

<sup>31</sup> 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.

<sup>32</sup> IVD Directive, Art. 16(1)

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

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

<sup>35</sup> 2010/C 83/02

<sup>36</sup> Treaty on the European Union, Article 6

<sup>37</sup> Treaty of the Function of the European Union, Protocol 30

<sup>38</sup> Article 7

States when they implement specific EU law<sup>39</sup>. With respect to privacy issues, the Articles of the EU Charter<sup>40</sup> 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 below<sup>41</sup>. 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 rights<sup>42</sup>. 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 generally<sup>43</sup>. 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 obligations<sup>44</sup>.

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 healthcare<sup>45</sup>. Where such a framework is in place, the State will not be in breach of the right to life<sup>46</sup>. The court gives States a margin of appreciation in respect of the provision of healthcare<sup>47</sup> 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 charge<sup>48</sup>. This has been translated by the NHS Constitution into a “right to receive NHS services free of charge”<sup>49</sup>. The Secretary of State and other health authorities have a duty to take the NHS Constitution into account in exercising their obligations.<sup>50</sup> 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.<sup>51</sup>

<sup>39</sup> Article 51

<sup>40</sup> Articles 7 & 8

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

<sup>42</sup> 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*

<sup>43</sup> *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

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

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

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

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

<sup>48</sup> Article 1(1)

<sup>49</sup> page 6 of *The NHS Constitution for England*, 26 March 2013, see also *The Handbook to the NHS Constitution for England*, 26 March 2013

<sup>50</sup> 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.

<sup>51</sup> 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

- 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 application of Article 2 in these circumstances, the English courts have generally refrained from interfering with the health authorities' discretion in respect of funding treatments<sup>52</sup>. 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 resources<sup>53</sup>. 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.<sup>54</sup>
- 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)."<sup>55</sup> 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 services<sup>56</sup>. 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*".<sup>57</sup> Prisoners who were denied treatment for HIV, including testing, have successfully alleged that this constituted a breach of Article 3.<sup>58</sup> 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*<sup>59</sup>, 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 return<sup>60</sup>. 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

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

<sup>53</sup> *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

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

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

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

<sup>57</sup> *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

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

<sup>59</sup> No. 30240/96 (2/5/1997) ECHR

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

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 public health. However, the ECtHR has stated that the confidentiality of information concerning HIV infection requires special protection<sup>61</sup>.
- 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.<sup>62</sup>
- 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 8<sup>63</sup>, 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.<sup>64</sup>
- 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 census<sup>65</sup>.

### **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 authorities<sup>66</sup> to protect children.<sup>67</sup> 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 Order<sup>68</sup> 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

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

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

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

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

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

<sup>66</sup> A local authority is an administrative body in local government

<sup>67</sup> 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

<sup>68</sup> Children Act 1989, section 44

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 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.<sup>69</sup> 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*<sup>70</sup>, 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

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

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

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 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 ¶72).
- 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.<sup>71</sup> 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.<sup>72</sup> 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 period<sup>73</sup> 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.<sup>74</sup> 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.<sup>75</sup>

<sup>71</sup> Equality Act 2010 Schedule 1 para.6

<sup>72</sup> 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>

<sup>73</sup> 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.

<sup>74</sup> Department of Health press release: Modernisation of HIV rules to better protect public

<sup>75</sup> 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](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](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”<sup>76</sup> 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.

<sup>76</sup> A and Others v The National Blood Authority and Others [2001] 3 All ER 298

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 treatment<sup>77</sup> 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

<sup>77</sup> 2<sup>nd</sup> ed., July 2009 ([https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/138296/dh\\_103653\\_\\_1\\_.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf))

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 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 guidance<sup>78</sup> 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.<sup>79</sup>

## **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 18<sup>th</sup> birthday, they are assumed to be a competent adult capable of consenting or refusing treatment, unless other factors prevent them from making informed decisions.<sup>80</sup> 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.<sup>81</sup> 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.<sup>82</sup>
- 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.<sup>83</sup>
- 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.

<sup>78</sup> Department of Health, *Health Protection Legislation (England) Guidance 2010*, 25 March 2010

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

<sup>80</sup> Family Law Reform Act 1969, section 1

<sup>81</sup> Family Law Reform Act 1969, section 8

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

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

### 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 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.<sup>84</sup>

#### 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 discussions<sup>85</sup>. 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.<sup>86</sup>

#### 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.<sup>87</sup>

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.<sup>88</sup> 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.<sup>89</sup>

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.<sup>90</sup> 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.<sup>91</sup> 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.

<sup>84</sup> UK National Guidelines for HIV Testing 2008

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

<sup>86</sup> UK National Guidelines for HIV Testing 2008 (page 10)

<sup>87</sup> *ibid*, page 11

<sup>88</sup> *ibid*, (page 4)

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

<sup>90</sup> *ibid*

<sup>91</sup> The NHS Constitution for England, 2013

Article 8 of the ECHR protects individuals' private lives against interference from the State. In addition, the NHS (Venereal Diseases) Regulations 1974<sup>92</sup> are designed to protect the 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'<sup>93</sup>. 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 Principles<sup>94</sup> stipulated in the 1998 Act. With regards to confidentiality, the 1998 Act obliges data controllers to implement measures to prevent unlawful access to the data<sup>95</sup>. In addition, controllers can only process data in accordance with a specified purpose<sup>96</sup> and the processing must be conducted fairly and lawfully<sup>97</sup>. 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 treatment<sup>98</sup>. 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 Act<sup>99</sup>. 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 audit<sup>100</sup>.
- 7.4.4 Data within the NHS concerning someone's STI status is subject to additional confidentiality requirements. The NHS (Venereal Diseases) Regulations 1974<sup>101</sup> 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 diseases<sup>102</sup> 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.*"<sup>103</sup>.
- 7.4.5 The NHS (Venereal Diseases) Regulations 1974<sup>104</sup> 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

<sup>92</sup> SI 1974/29

<sup>93</sup> 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

<sup>94</sup> The Principles are contained in Schedule 1 of the Act

<sup>95</sup> Schedule 1, 7<sup>th</sup> Principle

<sup>96</sup> Schedule 1 2<sup>nd</sup> Principle

<sup>97</sup> Schedule 1, 1<sup>st</sup> Principle

<sup>98</sup> Condition (4), Schedule 2 "*The processing is necessary in order to protect the vital interests of the data subject.*"

<sup>99</sup> Processing must comply with at least one condition stipulated in Schedule 3

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

<sup>101</sup> SI 1974/29

<sup>102</sup> Paragraph 8, September 2009

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

<sup>104</sup> SI 1974/29

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 this is impracticable<sup>105</sup>.

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*<sup>106</sup>.

## 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.

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

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

- 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 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.<sup>107</sup>

## **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.

## **8. WHAT ARE THE CRIMINAL IMPLICATIONS OF TRANSMITTING – OR BEING RECKLESS**

<sup>107</sup> 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'

## 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”<sup>108</sup> 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*”.<sup>109</sup> 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;<sup>110</sup> and
  - *Mens rea* - that the defendant had the intention to commit the criminal act.<sup>111</sup>
- 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]*<sup>112</sup>, 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’<sup>113</sup> and ‘Policy for prosecuting cases involving the intentional or reckless sexual transmission of infection’.<sup>114</sup> 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*”.<sup>115</sup> 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

<sup>108</sup> 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.

<sup>109</sup> *Haughton v Smith* [1973] 3 All E.R. 1109.

<sup>110</sup> *R v Deller* [1952] 36 Cr App Rep 184, CCA

<sup>111</sup> Expressions indicating this mental element include: ‘with intent’; ‘recklessly’; ‘maliciously’; ‘wilfully’; ‘knowingly’; ‘knowing or believing’; ‘fraudulently’; and ‘dishonestly’

<sup>112</sup> *R v Dica* [2004] 2 Cr App. R. 28

<sup>113</sup> Crown Prosecution Service Prosecution and Policy Guidance “Intentional or reckless sexual transmission of infection”

<sup>114</sup> Crown Prosecution Service Guidance “Policy for prosecuting cases involving the intentional or reckless sexual transmission of infection”

<sup>115</sup> 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.<sup>116</sup>
- 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.<sup>117</sup>
- 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.<sup>118</sup>

### 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.<sup>119</sup> 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).<sup>120</sup>
- 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.<sup>121</sup> 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.<sup>122</sup>
- 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.<sup>123</sup>
- 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.<sup>124</sup> 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).<sup>125</sup>
- 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

<sup>116</sup> *ibid*

<sup>117</sup> 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

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

<sup>119</sup> *ibid*, page 4

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

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

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

<sup>123</sup> *ibid*, page 4

<sup>124</sup> *ibid*, page 11

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

transmission; there have not been any successful prosecutions for intentional transmission, presumably because of the difficulty in proving a defendant's intention to transmit HIV.<sup>126</sup>

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.<sup>127</sup>

## 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.<sup>128</sup>

## 9. FURTHER INFORMATION

9.1 We have no further information to add.

Arnold & Porter (UK) LLP  
April 2014

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#### 10.5 Other Documents

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- ii) Terrence Higgins Trust: Prosecutions for HIV & STI Transmission or Exposure - A guide for people living with HIV in Scotland [http://www.tht.org.uk/sexual-health/Resources/Publications/Policy/Prosecutions-for-HIV-\\_and\\_-\\_STI-transmission-Scotland](http://www.tht.org.uk/sexual-health/Resources/Publications/Policy/Prosecutions-for-HIV-_and_-_STI-transmission-Scotland)
- iii) NAM Publications: HIV and AIDS Information: transmission as a criminal offence - Introduction to the legislation <http://www.aidsmap.com/Introduction-to-the-legislation/page/1504074/>
- iv) British HIV Association: Standards of care for people living with HIV in 2013 <http://www.bhiva.org/documents/Standards-of-care/BHIVASStandardsA4.pdf>
- v) National AIDS Trust, *Confidentiality in healthcare for people living with HIV*, Report: December 2009 <http://www.nat.org.uk/media/Files/Publications/Dec-2009-Confidentiality-in-healthcare-for-PLHIV.pdf>
- vi) MHRA press release, 'Regulator warns against purchasing all HIV and non-compliant self-test kits over the internet' 26 October 2011 <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON132075>
- vii) 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>

# SOUTHERN AFRICAN AIDS TRUST

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



Southern African AIDS Trust

Community Systems for HIV and  
Sexual & Reproductive Health & Rights

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We strengthen systems  
to create resilient  
communities across  
southern Africa

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