HIV transmission, the law and the work of the clinical team, 2010.

Matthew Phillips[1], Mary Poulton[2] on behalf of the British HIV Association (BHIVA) and British Association of Sexual Health and HIV (BASHH) writing committee
1 Trinity College Dublin; NHS North Western Deanery
2 Kings College Hospital NHS Foundation Trust

The writing committee members:
Mary Poulton (chair), *Kings College Hospital NHS Foundation Trust*
Jane Anderson, *Homerton University Hospital NHS Foundation Trust*
Yusef Azad, *National AIDS Trust*
James Chalmers, *School of Law, University of Edinburgh*
Anna Maria Geretti, *Royal Free Hospital NHS Trust*
Mark Nelson, *Chelsea and Westminster Hospital*
Chloe Orkin, *Barts and the London NHS Trust*
Matthew Phillips, *Trinity College Dublin; NHS North Western Deanery*
Lisa Power, *Terrence Higgins Trust, London*
Anton Pozniak, *Chelsea and Westminster Hospital*
Karen Rogstad, *Sheffield Teaching Hospitals NHS Foundation Trust*

DRAFT

Contents

1.Introduction and executive summary — Page 2

2. Current law regarding reckless HIV transmission — Page 4

3. Health care workers duties to patients and to others — Page 6

4. Recommendations for clinical practice — Page 12

5. Reckless transmission and vulnerable groups — Page 16

Appendix 1: Further scientific and legal information — Page 18

Appendix 2: Further sources of information — Page 21

References — Page 23

1. Introduction and Executive Summary

Prosecutions for reckless transmission of HIV have been brought in the UK since 2001 (Scotland) and 2003 (England & Wales). This has raised complex questions among medical practitioners as to their ethical and legal responsibilities related to HIV transmission, particularly around disclosure of information on HIV status. Although established generic ethical and professional principles continue to apply, certain features of the HIV epidemic have required special consideration. An underlying principle in the provision of clinical care for people with HIV is the need for a secure and confidential environment in which extremely sensitive matters can be frankly and fully discussed. The importance of ensuring that full trust is maintained by people with HIV in their clinical services in the light of the introduction of the criminal law into the HIV arena is fundamental, not only for the health of people living with HIV but also for people who may wish to seek information or testing and thus for the wider public health. This guidance document sets out these responsibilities and how these relate to the roles and responsibilities of health care professionals when caring for individuals infected with HIV.

1.1 Prosecutions

Individuals with HIV in England and Wales are only likely to be successfully prosecuted if they

- Knew they were HIV positive at the time of the alleged transmission
- Had unprotected sex with someone negative who subsequently tests positive and
- Did not disclose their HIV diagnosis before sex and
- Can be proven to be the only likely source of transmission

Consistent condom use (even without disclosure of HIV status) as evidence that the defendant was not reckless could be considered a reasonable defence.

The use of condoms together with disclosure in the event of breakage to enable sexual partners to access post-exposure prophylaxis (PEPSE) is likely to represent a reasonable defence against recklessness.

Scientific evidence alone will not provide sufficient evidence that the defendant is the source of transmission

1.2 Roles and responsibilities of Health Care Professionals.

Health care professionals have a central role to advise and support patients and to maintain confidentiality according to professional guidance and the law

For HIV positive individuals, advice must include the routes of HIV transmission and how to prevent transmission, with information about safer sexual practices and the use of condoms.

Discussion of sexual health needs must take place regularly according to relevant BASHH guidelines to enable the giving of appropriate advice.

There is individual and public interest in maintaining confidentiality; this may be outweighed in order to prevent serious harm to others.

It is important when considering breaching confidentiality to weigh up all potential harms as there may be situations where disclosure of HIV status to protect a sexual partner results in considerable harm to an individual e.g. domestic violence.

In situations where a health care professional believes that an HIV positive individual continues to put close contacts at risk their duties and subsequent action depend upon the type of contact (see figure one).

No information should be released to the police unless there is verified consent from the patient or there is a court order in place.

It is up to an individual patient to make a decision about complaining to the police and health care workers should remain impartial during discussions with patients.

DRAFT

Those involved (complainant and defendant) in cases of reckless transmission are likely to need specialist legal advice and support and referral to THT direct would be appropriate.

Sources of further information are listed in appendix two of this document.

1.3 Vulnerable Groups

There are special considerations with regards cases of alleged reckless transmission in those under 18 or anyone with learning difficulties as discussed in section 5.

DRAFT

2.1 Current Law regarding reckless HIV transmission

Successful prosecutions for transmission of HIV have been brought in the UK since 2001 (Scotland) and 2003 (England & Wales)[1,2] . It was formerly thought that the law (at least in England and Wales) did not cover the sexual transmission of disease. The charge used in England & Wales is inflicting "grievous bodily harm" under the 1861 Offences Against the Person Act[3]. In Scotland the charge is the common law offence of "reckless conduct". Neither of these charges were designed to be used on sexual transmission of disease, so there is in some instances doubt as to how the law might in fact be applied. In Scotland, the most recent prosecution included charges of exposure alongside one of transmission. Prosecutions for exposure would not be possible under English law, except in the unlikely event that an intention to transmit HIV could be proven. This area aside, the legal position in Scotland is broadly similar to that in England and Wales.

Charges are hard to investigate and even harder to prove, and the vast majority of allegations never reach court. Of those that do, however, there is a high rate of conviction and very long prison sentences in comparison to other uses of the same law. Even where the charges are dropped, police investigation of the allegations can be lengthy and personally highly damaging, usually involving extensive disclosure of status and detailed examination of sexual histories. Prosecutions to date in the UK have been disproportionately against heterosexual men, a number of whom were migrants[4,5], but can involve anyone with HIV.

Following extensive work by clinicians and community organisations with the Crown Prosecution Service and the Association of Chief Police Officers, and with the hindsight of about twenty court cases, some parameters are now clear in England & Wales. Someone with HIV in those countries is only likely to be successfully prosecuted if they

- Knew they were HIV positive at the time of the alleged transmission
- Had unprotected sex with someone negative who subsequently tests positive and
- Did not disclose their HIV diagnosis before sex and
- Can be proven to be the only likely source of transmission

Many allegations are made where nobody has been shown to be infected, and these have always failed so far. Increasingly, police are also unwilling to bring cases where it cannot be clearly shown that the accused is the only possible source of HIV transmission. Anyone making a charge needs to be prepared for close examination of their own sexual history, as well as that of the accused. Legal practice related to these prosecutions is still evolving and is likely to change in the future.

2.2 Transmission risk and recklessness

a. Condom use

It could be considered, according to the Crown Prosecution Service, a reasonable defence if someone had consistently used condoms even without disclosing their HIV status as this would be evidence that they were not 'reckless'. This has not been tested in the English & Welsh courts.

b. Plasma viral load on ART – Swiss statement.

A recent consensus statement from the Swiss Federal Commission for HIV / AIDS indicated that the risk of sexual HIV-1 transmission between discordant heterosexual couples should be considered negligible if the plasma viral load of the infected partner has been suppressed on HAART for at least 6 months and there are no sexually transmitted infections[6]. This statement, which received wide publicity in the specialist and community press, may lead some treated patients to interpret their status as non-infectious. It is important for clinicians to provide the correct guidance to patients on this point, by explaining that the Swiss position remains controversial and is not universally accepted. In addition, the evidence in support of the Swiss statement may not be generalised to all HIV-infected patients and should not be extrapolated beyond penile-vaginal intercourse as magnitude of risk is dependant on type of sexual intercourse[7].

c. Post exposure prophylaxis after sexual exposure (PEPSE)

If, immediately following sexual intercourse, it is realised that a partner has been exposed to a risk of HIV transmission, then the patient should always be advised to disclose to enable the exposed

DRAFT

individual to seek PEP[7]. Should transmission occur in this situation, it is not yet known if disclosure in this context would be considered a defence to reckless transmission. However, there is good reason to think that the use of condoms combined with disclosure in the event of condom breakage would not be regarded as "reckless".

2.3 Evidence of source of infection

Evidence based on the virus

a) Phylogenetic evidence: The use of phylogenetic evidence (genetic analysis of similarities between the viruses of two or more people) to support a transmission event has been widely reviewed and specific advice has been issued[8,9]. The analysis is useful for epidemiological studies on entire populations, but suffers from important limitations when applied to the study of individual transmission events. It can be helpful in indicating that two infections are not related, but cannot conclusively establish that transmission has occurred in a particular direction between two individuals. Therefore phylogenetic analyses should not provide the basis for assuming transmission and should only be used in the context of other and stronger supporting evidence.

b) Use of research/epidemiological data: The UK HIV Drug Resistance Database is a national repository for genotypic resistance tests performed as part of routine clinical care. This resource was developed solely for the purpose of scientific research, with the objective of enabling more effective clinical interpretation of the results of these tests. By the end of 2008 over 51,000 test results had been received and curated. Most of these (around 90%) are in the form of viral gene sequences. The potential use of these sequences in medico-legal cases of HIV transmission has been extensively discussed by the study Steering Committee, which has agreed the following policy:

- Sequences will not be released, either at an individual or epidemiological level, for medico-legal cases, including as "control" data for assessing sequence variability.

Further information can be found in appendix two.

Evidence based on temporal relationship to exposure

c) STARHS: Serological testing algorithm for recent HIV seroconversion makes it possible to establish whether or not an infection is likely to have been acquired in the last 4-6 months[10]. It is used by the Health Protection Agency as routine public health monitoring of all new HIV diagnoses in the UK. It is also used in some routine diagnostic settings. It is common for results to be returned to the patients and health professionals have a duty to ensure that the findings are interpreted and discussed correctly. In particular, such testing only gives an approximate indication of a recent HIV infection and several factors affect the test performance, including advanced HIV disease, the use of ART and infection with subtypes other than B. Results must therefore be treated with caution and should not be relied upon as evidence of recent transmission for the purposes of a prosecution for reckless transmission of HIV.

DRAFT

3. Healthcare workers' duties to their patients and to others

In general, the actions of health care workers are informed by ethical considerations, which are in turn regulated by the appropriate professional governing bodies. In the case of doctors this is the General Medical Council[11,12]. Many of the concerns faced by doctors when dealing with issues relating to the subject of reckless transmission are addressed in the generic GMC guidance. However there may be specific legal duties and legal consequences of the actions of health care workers that need to be understood. In this section these ethical duties and legal considerations are reviewed. There are not always definitive answers and interpretations may differ between experts, both legal and ethical.

3.1 The duty of confidentiality

Confidential information is both legally and ethically protected from disclosure. In law, "a duty of confidence will arise whenever the party subject to the duty is in a situation where he knows or ought to know that the other person can reasonably expect his privacy to be respected"[13]. A diagnosis of HIV or AIDS would ordinarily give rise to such a duty.

Confidentiality is not absolute. In particular, the public interest in maintaining confidentiality may sometimes be outweighed by another public interest favouring disclosure to a third party. Ultimately the public interest is decided by the courts. Furthermore, confidential medical information is not – in the UK at least – normally regarded as legally *privileged*, meaning that a healthcare worker cannot normally refuse to divulge it in court or in response to a court order.

Legal duty 1: A healthcare worker must maintain the confidentiality of patient information unless the patient has consented to disclosure or disclosure is necessary in the public interest. A failure to maintain confidentiality may give rise to legal liability.

3.2. The duty to properly advise

As well as maintaining confidentiality, a healthcare worker has an ethical duty both to the patient and third parties to properly advise his or her own patient with regards protecting others from infection. Not doing so could clearly result in transmission of HIV to a third party which in turn may be psychologically distressing to the patient knowing they have infected another individual.

Guidance on this point has been provided by the GMC in the following terms [14,para 9]

> You should explain to patients how they can protect others from infection, including the practical measures they can take to avoid transmission, and the importance of informing sexual contacts about the risk of transmission of sexually transmitted serious communicable diseases.

A failure to advise patients on protecting others from infection could result in a legal liability to pay compensation (negligence)[15,16]. Such liability has been imposed outside the UK and it is thought that courts in the UK would take a similar approach (examples in appendix 1)

Legal duty 2: A healthcare worker must properly advise a patient on ways of protecting their sexual partners from infection. A failure to do this may give rise to legal liability if the patient's sexual partner becomes infected as a result. Liability may also arise where a healthcare worker negligently fails to diagnose the patient as having the infection [17,18].

3.3. What if the healthcare worker believes that the patient is not following (or is unlikely to follow) the advice and putting close contacts at risk?

The matter is dealt with in the GMC's guidance on serious communicable diseases as follows

> **Informing sexual contacts of patients with a serious communicable disease**
> You may disclose information to a known sexual contact of a patient with a sexually transmitted serious communicable disease if you have reason to think that they are at risk of infection and that the patient has not informed them and cannot be persuaded to do so. In

DRAFT

such circumstances, you should tell the patient before you make the disclosure, if it is practicable and safe to do so. You must be prepared to justify a decision to disclose personal information without consent[14 para 10]:.

In circumstances such as those noted in the GMC guidance, a breach of confidentiality would probably be considered to be in the public interest, and therefore lawful.

This does not, however, answer the question of whether a healthcare worker can be legally *required* to breach confidentiality and disclose a patient's HIV-positive status to a close contact. In law, the relevant question is whether the healthcare worker can be said to owe a 'duty of care' to that close contact[19], so that they would be liable in damages if a breach of that duty (in this case, a failure to breach confidentiality where it was in the public interest to do so in order to protect that third party) caused the close contact to become HIV-positive.

Here, it is necessary to distinguish between three different categories of case.

(1) The close contact is also a patient of the healthcare worker
Because healthcare workers owe duties of care to their own patients, it is considered likely that the courts would recognise a duty by a doctor to disclose the HIV diagnosis to the close contact in such a case. A failure to disclose might therefore be a breach of the duty owed to the close contact, resulting in liability in damages if the contact became HIV-positive as a result.

(2) The close contact is not a patient of the healthcare worker
Although it has been suggested by at least one academic writer that the courts should recognise a legal duty to third party disclosure in such circumstances[19 para 2-90], the prevailing view is that no such legal duty exists [16, 20 pp. 70-71]. It is thought, however, that disclosure would be lawful because of the public interest in protecting the contact from infection. In other words, it is thought that there is a *power* to disclose, but no *legal obligation* to do so.

Where there is a risk to a known third party there is a duty to consider whether the benefits to the third party of disclosing the information outweigh the public and the patient's interest in keeping the information confidential. If disclosure is judged to be in the public interest, the information should be disclosed promptly. If there is no ongoing risk then the justification for disclosure may be lost. However, disclosure in the context of anonymous contact tracing in Genitourinary medicine settings may still be appropriate.

(3) There is no identified close contact
Where a patient has indicated that he or she does not intend to either practice 'safer sex' or disclose their HIV-positive status to future (unidentified) sexual partners, it would appear that there can be no legal duty of third party disclosure by health care workers for the simple reason that there is no identifiable person to disclose to. Disclosure clearly cannot provide an effective means of preventing onward transmission of HIV in such cases, as it is unclear to whom such disclosure would be directed. One's ethical duty here centres around trying to prevent ongoing transmission through ongoing counselling and support of the patient around safer sex practices to facilitate behaviour change where possible.

A caveat: the National Health Service (Venereal Disease) Regulations 1974
Some doubt has arisen as to whether disclosure to close contacts may *ever* be permissible given the terms of the National Health Service (Venereal Disease) Regulations 1974, regulation 2 of which provides as follows:

> Every Strategic Health Authority, NHS Trust, NHS foundation trust and Primary Care Trust shall take all necessary steps to secure that any information capable of identifying an individual obtained by officers of the Authority or Trust with respect to persons examined or treated for any sexually transmitted disease shall not be disclosed except –
>
> a. for the purpose of communicating that information to a medical practitioner, or to a person employed under the direction of a medical practitioner in connection with the

DRAFT

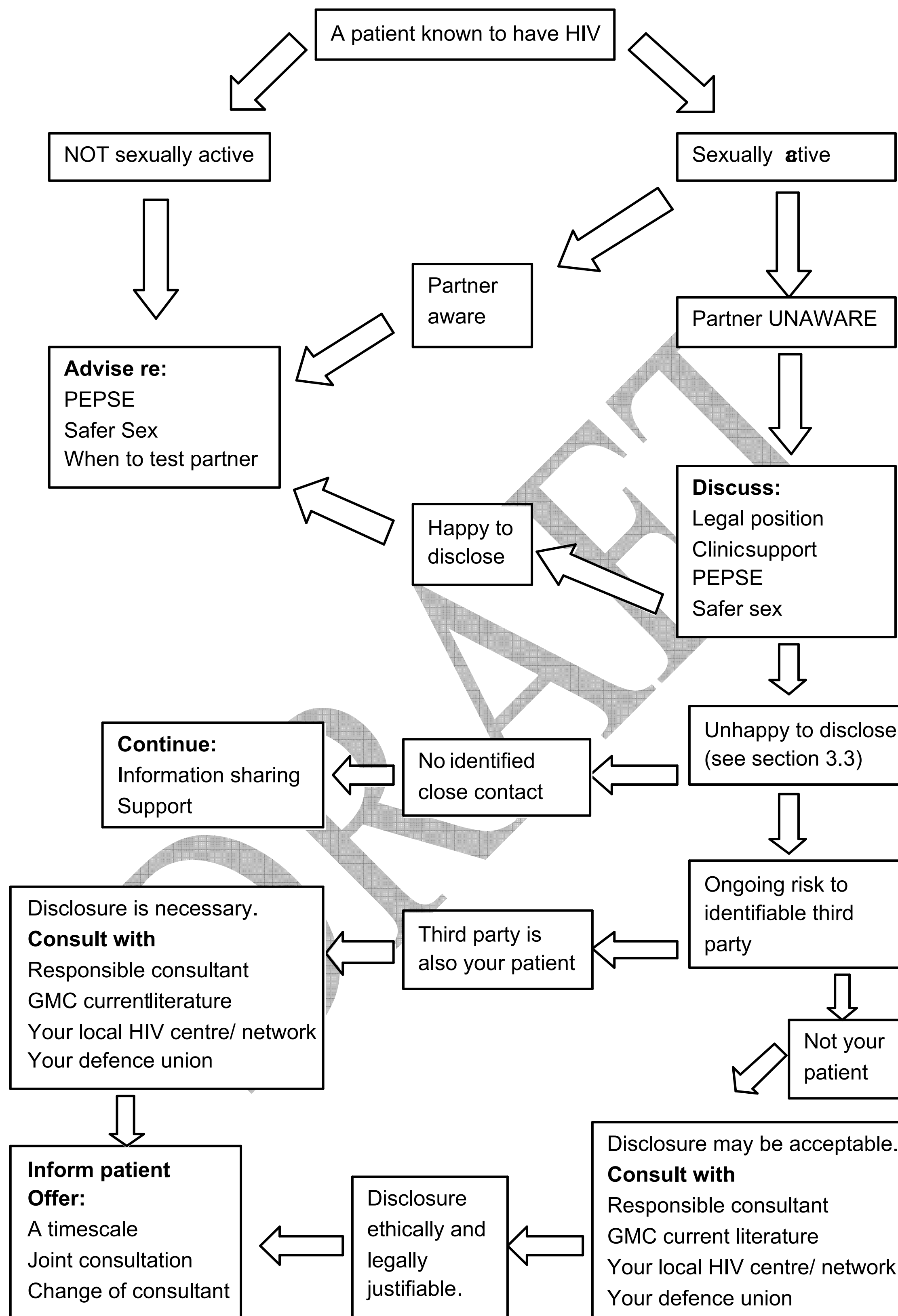
treatment of persons suffering from such disease or the prevention of the spread thereof, and

b. For the purpose of such treatment or prevention.

The effect of these regulations is not entirely clear and as they have never been subject of any court decision[20 pp. 72-74], there have been a number of different interpretations as to their meaning. The GMC has recently made it clear that its view is that the regulations “do not preclude disclosure if it would otherwise be lawful at common law, for example with the patient’s consent or in the public interest without consent” [14 p. para 3].

DRAFT

Figure 1Algorithm for disclosure to sexual partners



3.4. Disclosure to other healthcare professionals

The General Medical Council's guidance on confidentiality and serious communicable diseases provides as follows:

> You should make sure information is readily available to patients explaining that personal information about them will be shared within the healthcare team, including administrative and other staff who support the provision of care, unless they object, and why this is necessary[14 paras 7-8].
>
> If a patient refuses to allow you to inform someone outside the healthcare team of their infection status, you must respect their wishes unless you consider that failure to disclose the information will put healthcare workers or other patients at risk of infection. But such situations are likely to be very rare, not least because of the use of universal precautions to protect healthcare workers and patients, particularly during exposure-prone procedures.

The legal principles here are, in principle, little different from those involved with regard to disclosure to close contacts. Because of the public interest in preventing the onward spread of infection, disclosure may be a justified breach of confidentiality where it is necessary for this purpose. Because healthcare workers owe a duty of care not to put co-workers at risk, a failure to disclose might even give rise to legal liability where it was necessary to prevent another worker from a serious risk of infection. A purely hypothetical risk should not, however, be regarded as permitting disclosure without consent within the terms of the GMC's guidance.

However, such cases are likely to arise only very exceptionally indeed. In routine practice the use of **universal precautions** will be enough to protect health care workers from infection, thereby making disclosure unnecessary. Furthermore, it is each individual health care worker's personal responsibility to use universal precautions at all times for their own protection from blood borne infections, many of which are undiagnosed.

3.4.1. What if the risk to the close contact has become apparent as a result of doctors sharing information?

Where information has been legitimately shared between doctors as part of proper patient care, and one doctor has become aware of a risk to a close contact, a breach of confidentiality may be permissible (or required) in the same way as described in 3.3(3) above. Where information has been improperly shared, this creates a difficult situation.

Confidentiality applies to information which has been improperly passed on, but the sharing of information may result in a situation where (a) there is a duty to disclose to a close contact and (b) this will or may make apparent the earlier breach of confidentiality. It is important to avoid such situations arising by only sharing information about patients where this is in accordance with the GMC guidelines.

3.5 Disclosing information to the police.

If a patient has become HIV-positive as a result of potentially criminal actions by a third party, it is that patient's choice whether or not to bring it to the attention of the police. For a clinician to do so without that patient's consent is not legally required, and would be a breach of the patient's right to confidentiality. It is for the patient to decide to take that decision and to initiate it with appropriate legal guidance, **NOT** the health care provider. It is also inappropriate for doctors to place any pressure on an HIV positive patient to take legal action against a third party (or indeed not to take legal action). People living with HIV who wish to take such action are likely to have particular need for specialist advice and support(see 4.5 [d]).

There are limited circumstances in which doctors have an ethical duty to report criminal acts that have already taken place. GMC guidance recognises that, in rare instances, there may be a need for third

party disclosure in order to halt ongoing criminal activity or prevent criminal acts that might take place in the future [14 paras 53-55]:

> Disclosure of personal information about a patient without consent may be justified in the public interest if failure to disclose may expose others to a risk of death or serious harm. You should still seek the patient's consent to disclosure if practicable and consider any reasons given for refusal.
>
> Such a situation might arise, for example, when a disclosure would be likely to assist in the prevention, detection or prosecution of serious crime, especially crimes against the person. When victims of violence refuse police assistance, disclosure may still be justified if others remain at risk, for example, from someone who is prepared to use weapons, or from domestic violence when children or others may be at risk.
>
> If a patient's refusal to consent to disclosure leaves others exposed to a risk so serious that it outweighs the patient's and the public interest in maintaining confidentiality, or if it is not practicable or safe to seek the patient's consent, you should disclose information promptly to an appropriate person or authority. You should inform the patient before disclosing the information, if practicable and safe, even if you intend to disclose without their consent.

Requests for information from police (see section 4.6)
Health care professionals have no duty to answer questions that the police ask about their patients, unless the request is sanctioned by a court order. The paper and electronic medical records are owned by the NHS trust (hospital) or Secretary of State (GP records), and cannot be released without permission of the NHS trust (acute or primary care) within which they are held. Additionally medical records or information held within them must not be disclosed unless either a) the patient's consent, to the satisfaction of the consultant, is given or b) a court order has been issued. A police request in its own right makes no obligation to disclose. Care must be taken to remove any third party identifying information before disclosing the records.

3.6. Disclosing information in court

Although medical information is confidential it is not legally privileged. This means that if a health care professional is required to testify in court under oath all information must be disclosed. Failure to give such information would be a contempt of court.

Table 1: Guidance for disclosure to legal agencies:

	COURT ORDER	POLICE REQUEST
Initial Request	Information specified must always be disclosed after following trust guidelines.	This must be accompanied by consent. The consultant must go to reasonable lengths to discuss with the patient to ensure this consent is valid. There is no obligation to disclose information.
Patient consent for disclosure	Patient's consent is not required, however it would be best practice to inform the patient the request has been made.	Patient consent must be obtained and valid.
Information sharing	All trust guidelines for information sharing must be satisfied before disclosing any information, even for a court order. Third party information must be removed prior to information sharing, unless explicitly asked for in a court order.	

DRAFT

4. Recommendations for Clinical Practice

4.1 The ethical decision making process

When faced with an ethical dilemma in medicine the process of decision-making needs to be of the highest integrity and must be clearly documented. Clearly one must operate within the law and follow professional ethical guidance as from the GMC. As highlighted in section 3, there are areas where the law remains uncertain and no one case is exactly the same as another, so any guidance will always be incomplete. It is important therefore that all ethical decisions are made on a case by case basis, identifying and balancing all relevant harms and benefits. In considering a course of action one should ask, is this a reasonable action to take and how is this action justified? For example, when considering disclosure of HIV status to a third party, if the justification is to prevent ongoing risk of HIV transmission, then there must be continued risk of HIV transmission, such as unprotected sexual intercourse for this justification to hold. See Figure 1.

Normally, the overall responsibility for the patient rests with the consultant of record. However, care is delivered within a multidisciplinary team and decision-making should involve all relevant team members. Clear lines of responsibility and accountability with mechanisms for discussion amongst team members should exist in all clinical services with responsibility for the care of people with HIV infection. Additionally, mechanisms must be in place for the appropriate education and support of health care professionals in this rapidly evolving area. If unavailable locally such mechanisms should be available within existing managed clinical networks. All healthcare professionals working with people with HIV must be familiar with the ways in which data is stored and the confidentiality of medical information is maintained within their service and be able to explain this to patients as required. If a consultant finds her/himself in the unusual position of being responsible for the care of two patients with HIV, who are complainant and defendant in a prosecution for reckless transmission, there may be a conflict of interest which will be detrimental to the therapeutic relationship and it may be appropriate to transfer the care of one patient to a consultant colleague.

4.2 The roles and responsibilities of health care professionals

The particular roles of health care professionals caring for individuals infected with HIV are:

- To advise patients with HIV appropriately about HIV infection and the implications for themselves and others.
- To support patients with HIV appropriately.
- To ensure confidentiality of medical information in line with GMC guidance
- To keep meticulous records of all consultations, including advice given over the telephone, as well as copies of e-mail correspondence with patients, in line with Royal College of Physicians' and General Medical Council guidance [11,21].

4.2.1. Advice that should be provided by the clinical team to all patients diagnosed with HIV infection

a. Giving proper, up to date, relevant advice in a way that people with HIV can fully understand (e.g. taking into account language, cultural sensitivities, educational level, literacy and other factors) is critical. All advice given by members of the multidisciplinary team to people living with HIV must be consistent and care should be taken to avoid any conflicting messages. Clinical teams may wish to review the information given to patients to ensure consistency within the team. Any advice should be provided in both verbal and written forms in appropriate language, ensuring the patient understands.

b. Giving advice is an ongoing process and clinicians should discuss sexual behaviour and assess sexual and reproductive health needs regularly with patients according to relevant BASHH guidelines[22], ensuring that advice given is appropriate to the patient's circumstances and needs.

c. All people living with HIV should receive Information from their clinical team regarding the nature of HIV infection, its routes of transmission, and the ways in which HIV transmission can be reduced. In particular details about the correct use of condoms to prevent transmission should be provided,

DRAFT

together with information about safer sexual activities and their relative risks. Such information is not only important for the well being of third parties but also for the person living with HIV for whom risks of transmission to someone else may be personally very distressing.

d. The link between plasma viral load and sexual transmission of HIV should be discussed (refer to 2.2. [b]).

e. Information should be given that HIV infection is not outwardly visible and no assumptions about the HIV status of sexual partners should be made without specific discussion.

f. People living with HIV should be advised that sharing information about an HIV diagnosis with sexual partners provides the best way of allowing informed decision making about sexual behaviour for all the parties concerned.

g. People living with HIV should be advised about the availability and utility of post-exposure prophylaxis following unprotected sexual intercourse or a condom split (PEPSE). This should be documented. This will mean that the patient may have to disclose the HIV infection risk at some stage, possibly post facto. Disclosure to enable a partner to seek PEPSE and thus reduce the risk of transmission of HIV is the appropriate and responsible course of action in this situation.

h. People with HIV should be advised that that there have been successful prosecutions when transmission of HIV has been proved to have taken place. Care needs to be taken in the way that this information is imparted to patients. It is crucial for an ongoing therapeutic relationship that it is perceived neither as a threat nor as a means whereby clinical staff impose their own beliefs on their patients. It should be advised that the risk of prosecution is higher if the patient:

> a. has not disclosed the fact of his/her HIV infection to the sexual partner before having unprotected intercourse.
> b. has only disclosed his/her HIV infection after having unprotected sex.
> c. has given false information to a partner about their HIV status for the purposes of unprotected sexual intercourse.

i. People with HIV need to recognise that the best clinical attention will be given by healthcare workers who are aware of the patients' complete medical history. This requires appropriate sharing of medical information with other healthcare professionals involved in the patients care.

4.2.2. Support by clinical staff for People with HIV

a. In a GUM clinic setting health advisors will normally start discussion about and support for the process of disclosure after diagnosis. Anyone needing additional support should be given further health advisor appointments as necessary. It is however incumbent upon all members of the team to provide support and advice as required or to refer appropriately.

b. Clinical staff involved in the care of people with HIV need to acknowledge that disclosing HIV infection to partners can be very difficult and frequently fraught with anxieties about the perceived outcome [23,24]. Patients should be helped to understand that they will need to come to terms with their diagnosis as part of the process of disclosure. It is important that individuals are given enough time and appropriate support according to their individual needs.

c. Disclosure should be seen as a process rather than an event and patients given support throughout that process. There should be discussion and agreement about an appropriate time frame for disclosure wherever possible. It should however be borne in mind that this is not the approach usually taken by the courts, where disclosure is seen as immediate and instantaneous.

d. The clinical team should give patients information about, and where necessary direct referral to, additional sources of support, peer groups and voluntary sector agencies. Appropriate leaflets and the details of sources of specialist information should be available in all clinical settings in appropriate languages and formats

e. In circumstances of non-disclosure, this should be discussed sensitively on an individual basis to establish barriers that exist and provide support in addressing these.

f. It is important that the issues of disclosure are revisited and as circumstances change appropriate advice and support are made available. If a complex case of continued non-disclosure arises, it will be important for the named consultant and members of the MDT to make disclosure decisions based on current GMC good practice and relevant to the current legal situation. See Figure 1.

g. It is important to provide information on the data that are kept about patients and the duties of confidentiality of health care professionals in protecting such data to ensure that the clinical setting is perceived as a safe arena for full and uninhibited discussion of the situation facing the patient.

4.2.3. Advice and support for patients involved in potential cases of reckless HIV transmission

a. Individuals who believe they may be the injured party in a case of reckless transmission and those accused of recklessly transmitting HIV must be given all the advice appropriate to any person living with HIV, and offered PEPSE if appropriate[25.]

b. Some patients may express a wish to bring criminal charges against a sexual partner. In this situation it is important that the patient is given time to discuss the implications of this approach with an appropriately trained and experienced member of the team, for example Health Advisor or Clinical Nurse Specialist as per local arrangements.

c. Ultimately it is for the patient to decide if they wish to bring the issue to the attention of the police, and not the role of the health care worker.

d. In addition both the accused and complainant will need specialist legal advice and peer support. Appendix two has a directory of further sources of information and support to which they may be signposted. In particular, THT Direct is staffed by workers trained specifically in these issues and onward referral for support would prove useful.

4.2.4. Requests for Information by the Police

Information may be requested as part of an investigation of alleged reckless HIV transmission. This may pertain to claimant, defendant or sexual contact(s) of a claimant or defendant; the same process should be followed in each case.

All clinical services should develop local guidance about actions to be taken in the event of police enquires. These should include the following:

Any requests from the police for information about patients should, in the first instance, be directed to the consultant in charge of the patient's case. The consultant must be absolutely satisfied that the patient's consent is valid, and every attempt should be made to discuss this in person with the patient. If the patient has a legal representative through whom communications can be made, then they should be part of this process.

Local trust protocols must be followed and Trust level management and legal advisers should be informed of any such request as necessary.

When releasing records, attention must be paid to the fact that Genitourinary medicine notes may hold personal details of third parties (contact tracing). These must be removed before releasing notes to external agencies.

With regards to tracing other (sexual) contacts of claimant or defendant identified as part of an ongoing investigation then it is best if contact tracing is carried out by local sexual health services as opposed to the police. Therefore police may also request that a person be contacted with a request that they have an HIV test. This may be to identify other people possibly infected by the accused, or other people who may possibly have infected the complainant.
In approaching individuals either requesting consent for information to be disclosed, or with a request that they be tested for HIV since there is a possibility they may be at risk, it is important to state clearly that the approach has been prompted by a police investigation into a third party. Although the

DRAFT

police may have an interest in the results of such testing, information on individuals must not be disclosed to the police without their consent or a court order.

DRAFT

5. Reckless transmission and Vulnerable Groups.

The Under- 18s

Young people under the age of 18 years old are in law children, those under 16 years cannot legally have sexual intercourse, and those under 13 years are deemed unable to consent to any sexual activity. Adults usually assume younger adolescents are not sexually active. In reality at least 25% have had sexual intercourse by their 16th birthday and most do not use condoms at first sexual intercourse.

The onus is on healthcare professionals and the voluntary sector to ensure that the young person realises the risks of unprotected sex both to themselves and others. Information given to HIV positive adolescents must be the same as that given to adults on this issue, including criminal liability. The way the information is given must be tailored to the physical, emotional and intellectual maturity of the young person. The information will need to be revisited but using different terms and language as they mature and their understanding increases. In order to be effective, information on use of condoms and reckless transmission needs to be given to young people before first sexual activity. If information is not given and transmission does occur the health care provider could be said to have failed in their ethical duty to the patient and potentially be held legally responsible (see section 3.2 on duty to properly advise). This could also apply if the young person has not been told they are HIV positive by parents/carers or healthcare providers, for whatever reason. Although there would be no criminal liability, there is a potential for civil charges (negligence) to be brought.

Reckless transmission does not occur if the sex partner is aware of the diagnosis and chooses not to use condoms. However in the case of adolescents their partner is likely to be of a similar age and may not be *competent* and have sufficient understanding to agree to non-use of condoms, even if disclosure of HIV positive status had been made.

5.1 Recommendations in the event of an accusation against, or by, someone younger than 18

a. Such cases should be managed within the local trust frameworks for assessing risks of sexual abuse against younger people, and according to nationally developed protocols, such as BASHH guidelines for management of STIs in children and young people[26].

b. The competency of both the accused and accuser to consent to sexual intercourse and therefore accept the risk of transmission should be assessed.

c. Should someone below 18 be subject to investigation, the Youth Offending Service can provide invaluable support for protecting their individual needs.

d. Any interview which is legal or has legal implications, should take place in the presence of a responsible adult (this need not be a parent or legal guardian, depending on the young person's choice).

e. Specialist legal advice and representation is important and the young person and/or their carers should be directed to THT direct.

f. Confidentiality of the young person has many potential chances of being accidentally breached, given that multi-agency care is sometimes necessary. It will be vital to breach confidentiality only as far as absolutely required.

Individuals with Learning Difficulties

Those with learning difficulties will need extra support, both accuser and accused. If someone or their carer wishes to bring a charge, then services such as, hospital/ community special needs teams, adult safeguarding teams and practitioners skilled in determining competency (such as psychologists or psychiatrists) need to be involved early on in any inquiry. In addition, with the patient's/ carer's

DRAFT

permission, any key workers or contact points already known by the accused should be involved. For those who are accused, it must be borne in mind that the stress of such an inquiry may be magnified by their particular difficulty. If there is a key worker available, then they would be a good locus for co-ordination of emotional/psychological support. Again, it will be necessary to have competency assessed as this will be key to whether a prosecutable activity has taken place.

DRAFT

Appendix 1: Further Scientific and Legal Information

This appendix holds extra information germane to the issues covered in these guidelines.

The Swiss Statement, Transmission Risks & The International Arena

The Swiss Statement

The Swiss Federal Commission for HIV/AIDS consensus statement on the effect of treatment on transmission (SFHCA) statement was released at the beginning of 2008, and stated that HIV positive people who are receiving effective antiretroviral treatment, defined by an HIV RNA level less than 40 copies per mL, cannot transmit the disease to an HIV-negative partner via unprotected sexual contact[6].

It is important for clinicians to provide the correct guidance to patients on this point, by explaining that the Swiss position remains controversial and is not universally accepted. In addition, the evidence in support of the Swiss statement may not be generalised to all HIV-infected patients and should not be extrapolated to anal intercourse, particularly if receptive and accompanied by ejaculation, which carries a greater risk of transmission. The issue of co-existence of sexually transmitted infections is also complex. Some of the infections that are known to facilitate HIV transmission can be easily detected and treated. However, others are either not routinely tested for or cannot be eliminated, the classical example being symptomatic or asymptomatic genital herpes simplex virus (HSV) infection[27]. Discordance between plasma and genital HIV-1 RNA load has been widely reported [28,29,30]. Assessment of HIV-1 RNA load in seminal plasma has been suggested by some as a way to assess infectivity. The measurement of seminal viral load is well established in practice for testing of sperm to be used for in vitro fertilisation and the results strictly apply to the specimen being teste[30]. There is no evidence to support the use of seminal viral load testing to ascertain the general infectivity of a person. Available evidence indicates that HIV-1 shedding in the genital tract can be intermittent and therefore a single result is unlikely to reassure about infectivity.

Correlations between levels of HIV in blood and semen were investigated in 19 studies and ranged between 0.07 and 0.64[31]. A consistent finding was that viral load was lower in semen than blood. In most of the studies, men who had undetectable virus in their semen also usually had an undetectable viral load in their blood. But two studies identified individuals who had levels of HIV in their semen that were equal to or greater than in their blood. Four factors were identified that could potentially influence the relationship between viral load in blood and semen: sexually transmitted infections; anti-HIV therapy and adherence; drug resistance; and the stage of HIV infection.

Legal Implications

Following the Swiss statement there were a number of cases heard internationally, of the equivalent of reckless transmission within their jurisdiction, where the Swiss statement was explored as part of their deliberations. Below is a summary of some of them:

- Geneva Court of Justice, February 2009. 18 month prison sentence of a 34 year old African man quashed,. He had been convicted under Swiss law, under article 221, of attempting to engender grievous bodily harm. However, Professor Bernard Hirschel, who was one of the authors of the Swiss statement, testified that the risk of transmission per event was less than 1 in 100,000 as the appellant was on HAART[32].
- Court of Appeals for the Armed Forces, May 2008. An HIV positive soldier had his conviction of risk exposure to 2 women he had not disclosed his status to re-examined, as he had been on successful HAART at the time of intercourse. However, he did not have his conviction set aside[33].
- Canadian courts, July 2008. A case of an HIV positive man who had unprotected sex with six women was examined, and the Swiss statement was explored. However, the judge found that neither the CDC nor WHO/UNAIDS agreed with the Swiss statement, and so the conviction was made[34].

DRAFT

Counter Evidence.

A simple mathematical model was published that estimated the cumulative risk of HIV transmission from effectively treated HIV-infected patients (assuming HIV RNA less than 10 copies per mL) to their HIV-negative partners over a long period of time[35]. The risk of unprotected sexual exposure was explored in this situation, both for single acts and over a long period of time.

Assuming that each year, each couple has 100 unprotected sexual encounters, the cumulative probability of transmission is:

- 0.22% for female-to-male transmission,
- 0.43% for male-to-female transmission,
- 4.3% for male-to-male transmission.

For example, in a population of 10,000 partnerships initially discordant for HIV, after ten years the expected number of HIV infections would be 215 from female-to-male transmissions, 425 from male-to-female transmissions, and 3,524 from male-to-male transmission. This new population would indicate an incidence rate four times current rates, when condoms are encouraged.

The authors' analyses suggest that the risk of HIV transmission in heterosexual partnerships in the presence of effective treatment is low but non-zero and that the transmission risk in male homosexual partnerships is high over repeated exposures.

UK Policies & Points of Law

National Health Service (Venereal Disease) Regulations 1974

This was discussed in section 3.3, and how the terms of this regulation might theoretically preclude release of information pertaining to sexually transmitted illnesses. It will be noted that the regulation is not in its terms directed to healthcare workers themselves, but only to the named bodies. The effect of the regulation is not entirely clear; if the regulation were interpreted as placing an absolute prohibition on disclosure by healthcare workers employed by the named bodies, then this would suggest that the GMC guidelines on serious communicable diseases, as quoted before, are incorrect in their terms. Although this is an unlikely interpretation, their meaning has not been the subject of any court decision, with the unfortunate consequence that it is impossible to be absolutely certain about the legal position[20]. In *Health Protection Agency v X* (2005)[36] there was no ruling made on this point, but the GMC made it clear that its view is that the regulations "do not preclude disclosure if it would otherwise be lawful at common law, for example with the patient's consent or in the public interest without consent"[14 para 3]. With this in mind, the Regulations should not be regarded as an absolute barrier to disclosure, which should be considered on a case-by-case basis in accordance with the principles outlined earlier in this paper. As a result of this case in 2006 the Department of Health published a consultation document on these regulations. The final outcome of this is yet to be reported[37].

Public Health (Control of Disease) Act 1984

Following recent reforms to the Public Health (Control of Disease) Act 1984, there are now in theory powers under section 45G of that act empowering a court to impose coercive orders on a person who it is thought could pass on an infection presenting significant harm to human health, but draft guidance from the Department of Health and Health Protection Agency counsels against the use of these powers in relation to HIV and sexual health.

Third Person Liability.

This was discussed in section 3.2. It was shown that although liability to third parties has not yet been established in UK courts, there are international examples of such liability being imposed.

Examples:

1. In a US case, a blood technician was exposed to the risk of Hepatitis B infection by a needle stick injury. Doctors negligently advised her that if she remained symptom-free for six weeks this would mean she was not infected. Following this advice, she resumed sexual relations with her partner after eight weeks. It was held that her doctors could be liable to
pay damages to her partner when he developed Hepatitis B as a result[17].

2. In an Australian case, a doctor negligently failed to consider that a patient of his might be HIV-positive despite a history and symptoms which would have led ‘a general practitioner exercising ordinary care and skill [to] have considered a diagnosis of HIV and counselled the need for an HIV antibody test’. The doctor was held liable in damages to a subsequent sexual partner of his patient, who contracted HIV[18]

<u>The UK HIV Drug Resistance Database</u>

This database and its purpose was described in section 2 (3). Its steering committee agreed a policy for how its data could be used, and only the pertinent part was shown above. The full policy concerning data ownership and sharing is as follows:

- Individual sequences are considered to be owned by the patient’s clinician, and the sequence itself or any information derived from it will not be released without his/her express consent.
- Sequences will not be released, either at an individual or epidemiological level, for medico-legal cases, including as “control” data for assessing sequence variability.
- The Coordinating Centre will continue to maintain the highest level of IT governance and security. In particular, files of sequences released to scientific collaborators for molecular epidemiological analyses are completely anonymised and cannot be linked back to the central database, thus ensuring that patient confidentiality is not jeopardised.

DRAFT

Appendix 2: Further Sources of Information

Web Based Resources:

THT “Policing Transmission’: relating to transmission of HIV in England & Wales, 2005-2008.
Accessible online 25/03/10
http://www.tht.org.uk/informationresources/publications/policyreports/policingtransmission950.pdf

UNAIDS paper: Criminalization of HIV
Accessible online 25/03/10
http://data.unaids.org/pub/BaseDocument/2008/20080731_jc1513_policy_criminalization_en.pdf

Crown Prosecution Service: Policy for prosecuting cases involving the intentional or reckless sexual transmission of infection
Available online 25/03/10
http://www.cps.gov.uk/publications/prosecution/sti.html

Web based information about criminalisation of HIV transmission for people living with HIV:

THT
Accessible online 25/03/10
http://www.tht.org.uk/informationresources/prosecutions/whatthelawsays/

NAT
Accessible online 25/03/10
http://www.nat.org.uk/Living-with-HIV/Useful-information/Criminal-prosecutions.aspx

NAT/THT joint leaflet: Guidance on Criminal Prosecutions for people living with HIV.
Accessible online 25/03/10
http://www.nat.org.uk/Media%20library/Files/PDF%20documents/2009/Feb/NAT-THT%20Guide%20re%20Prosecutions%20May%202009%20Single%20Pages.pdf

Relevant Organisations:

British HIV Association
BHIVA Secretariat:
1 Mountview Court, 310 Friern Barnet Lane, London N20 0LD
Telephone: +44 (0)20 8369 5380
Facsimile: +44 (0)20 8446 9194
Email: bhiva@bhiva.org
Web: http://www.bhiva.org

British Association of Sexual Health and HIV
BASHH Secretariat:
Royal Society of Medicine, 1 Wimpole Street, London W1G 0AE
Telephone: +44 (0)20 7290 2968
Fax: +44 (0)20 7290 2989
Email: bashh@rsm.ac.uk
Web: http://www.bashh.org/

African HIV Policy Network (AHPN)
New City Cloisters, 196 Old Street, London EC1V 9FR
Telephone: +44 (0)20 7017 8910
Fax: +44 (0)20 7017 8919
Email: info@ahpn.org
Web: http://www.ahpn.org/contact/index.php

DRAFT

National AIDS Trust
Telephone: +44 (0)20 7814 6767
After hours number: +44 (0)20 7814 6767 (5pm-9am)
Fax: +44 (0)20 7216 0111
E-mail: info@nat.org.uk
Web: http://www.nat.org.uk/contact/index.cfm

Sigma Research
University of Portsmouth, 77a Tradescant Road, London SW8 1XJ
Telephone: +44(0)20 7820 8022
Fax: +44 (0)20 7793 8009
Email: admin@sigmaresearch.org.uk
Web: http://www.sigmaresearch.org.uk

The Terrence Higgins Trust
Terrence Higgins Trust Direct
Telephone: 0845 12 21 200
Web: www.tht.org.uk

DRAFT

References:

1. Nyambe, M. *A rapid scan of the laws and rates of prosecution for HIV transmission within signatory states of the European Convention of Human Rights.* s.l. : Terence Higgins Trust, 2004.
2. National AIDS Trust. Criminal prosecution of HIV transmission, NAT policy update. *National AIDS Trust.* [Online] 2005. http://www.nat.org.uk/natuk/policy.cfm?id=11.
3. Sigma Research. *Grievous Harm? Use of the Offences Against the Person Act 1861 for sexual transmission of HIV: A Briefing Paper.* London : Sigma Research. ISBN 1 872956807.
4. Weait M Criminal Law and the Sexual Transmission of HIV: R vs Dica (121-134). *Modern Law Review.* 2005.
5. Weait M Knowledge, Autonomy and Consent: R v Konzani (163-172). *Criminal Law Review.* 2005, October.
6. Vernazza, P. Les personnes seropositives ne souffrant d'aucune autre MST et suivant un traitment antiretroviral efficace ne tranmettent pas le VH par voie sexuelle. *Bulletin des medicins suisses.* 2008, Vol. 89, 5.
7. Peabody R (Ed) (2009) *HIV transmission and testing.* NAM, London.
8. Pillay, D, et al. The use of HIV phylogenteics . Virological evidence within HIV criminalisation cases is of limited value in proving transmission (460-461). *British Medical Journal.* 2007, Vol. 333.
9. Bernard, EJ, et al. HIV forensics: Pitfalls and acceptable standards in the use of phylogenetic analysis as evidence in criminal investigations of HIV transmission (382-387). *HIV Medicine.* 2007, Vol. 8.
10. Chawla, A, et al. HIV antibody avidity testing to identify recent infection in newly diagnosed HIV-1 seropositive persons infected with diverse HIV-1 subtypes (415-420). *Journal of Clinical Microbiology.* 2007, Vol. 45.
11. General Medical Council. *Good Medical Practice.* London: GMC, 2006.
12. General Medical Council. *Confidentiality* London: GMC, 2009.
13. *Campbell v MGN Ltd [2004] 2 WLR 1232 per Lord Hope of Craighead at para 85.*
14. General Medical Council. *Confidentiality: Disclosing Information about Serious Communicable Diseases.* London : GMC, 2009.
15. Grubb A and Pearl, D. HIV transmission: doctor's liability to future partner (250-6). *Medical Law Review.* 1990, Vol. 40.
16. Chalmers, J. Criminalisation of HIV transmission: can doctors be responsible for the onwards transmission of HIV? (782-787). *International Journal of STDs and AIDS.* 2004, Vol.15.
17. *DiMarco v Lynch Homes-Chester County, Inc 583 A.2d 422 (pa.1990).*
18. *BT v Oei[1999] NSWSC 1082.*
19. Jones, M. *Medical Negligence (3rd Edition).* London: Sweet and Maxwell, 2003.
20. Jones, M. *Legal Responses to HIV and AIDS .* Oxford: Hart Publishing, 2008.
21. Royal College of Physicians. Generic Record Keeping Standards. http://www.rcplondon.ac.uk/clinicalstandards/hiu/Documents/GenericRecordKeepingStandards.pdf
22. Fakoya A, Lamba H, Mackie N et al. 2007 Joint BHIVA-BASHH-FFP UK guidelines for the management of sexual and reproductive health (SRH) of people living with HIV infection. http://www.bashh.org/documents/91/91.pdf
23. Terrence Higgins Trust:Policy Campaigns and Research Division. *Social Exclusion and HIV: A Report .* London : Terence Higgins Trust, 2001.
24. Dodds C, et al. *Outsider Status: stigma and discrimination experienced by Gay men and African people with HIV.* London : Sigma Research, 2004.
25. Fisher M, Benn P, Evans B et al . UK guideline for the use of post-exposure prophylaxis for HIV following sexual exposure. Int J STD and AIDS 2006; 17:81-92
26. Rogsatd KE, Thomas A, Williams O et al. *Management of STIs in Children and Young People.* Int J STD & AIDS (in press) 2010.
27. Ramaswamy M and Gerretti, AM. Interactions and management issues in HSV and HIV co-infection (231-243). *Expert Review of Anti-Infective Therapy.* 2007, Vol. 5.
28. Butler et al. *Poster 49 LB.* s.l. : CROI, 2009.
29. Sheth et al. *Poster 50.* . s.l. : CROI, 2009.
30. Marcelin et al. *Poster 51.* s.l. : CROI, 2009.
31. Kalichman SC et al. *Human immunodeficiency virus load in blood plasma and semen: review and implications of empirical findings*. Sexually Transmitted Diseases 35: 55 – 60, 2008.
32. BGE 134 IV 193
33. *United States v. Dacus*, No. 07-0612/AR

DRAFT

34. *R. v. Mabior*, 2008 MBQB 201
35. Wilson DP, Law MG, Grulich AE et al. *Relation between HIV viral load and infectiousness: a model-based analysis.* Lancet 2008; 372: 314-20
36. *Health Protection Agency v X[2005] EWHC 2989(Fam).*
37. Department of Health. *Policy Consultation on Confidentiality and Disclosure of Patient Information: HIV and Sexually Transmitted Infections.* s.l. : HMSO, 2006.

DRAFT