

# UNITED KINGDOM NATIONAL GUIDELINES ON HIV TESTING 2006

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British Association of Sexual Health and HIV**

## Introduction and Methodology

### Scope and purpose

Since 1995 the uptake of Highly Active Antiretroviral Therapy (HAART) in the United Kingdom (UK), has resulted in a two-thirds reduction of death from AIDS <sup>1</sup>. Health care workers can be increasingly confident when discussing with people whether to test for HIV infection, the benefits from knowing the diagnosis.

The main objective of these guidelines is to reduce the number of undiagnosed HIV infections in patients visiting Genitourinary Medicine (GUM) Clinics. Allowing the opportunity for improvement in the health and well-being of individuals through access to medicines; improvement in the Public Health from the expected reduction in onward transmission; and patient empowerment in knowing their status.

Recent estimates suggest that there are an estimated 58300 people living with an HIV infection in the UK, of whom 19700 remain undiagnosed<sup>1</sup> The National Strategy for Sexual Health and HIV<sup>2</sup> has set HIV testing targets for GUM services: to offer HIV testing to all GUM clinic attendees by the end of 2004 with a view to increasing the uptake to those offered it to 40% by the end of 2004 and to 60% by the end of 2007. By the end of 2007 it is hoped that the number of previously undiagnosed HIV positive people attending clinics is reduced by 50%.

These guidelines offer recommendations (see box 1 for summary) on:

- When to test for HIV
- How to test for HIV
- Pre-test discussion, informed consent and confidentiality
- Insurance issues
- Methods to increase the uptake of testing
- Methods of giving results

They should enable health care professionals, who are considering offering HIV testing to their patients, to obtain informed consent after providing appropriate information.

It is aimed primarily at people aged 16 years or older (see specific guidelines for those under 16<sup>3</sup>) presenting to health care professionals working in GUM departments within the United Kingdom. However, the recommendations should prove useful across similar settings, including general practice and general medicine.<sup>4</sup>

The recommendations in this guideline may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on the professional judgement of the clinician, consideration of individual patient circumstances and available resources.

### Stakeholder involvement

The guideline have been produced by a multidisciplinary group comprising of: Consultants in GUM/HIV, health adviser, nurse, a representative of MedFASH (Medical Foundation for AIDS and Sexual Health, formerly BMA Foundation for AIDS), a representative of the Terrence Higgins Trust (THT), a Virologist from the Health Protection Agency (HPA, formerly the PHLS), a General Practitioner and a public health scientist from the Medical Research Council.

The THT was the main source of patient input.

### Rigour of Development

Evidence for these guidelines was provided by review of the Cochrane Library, Medline, Embase, conference proceedings and other guidelines up to December 2004. Articles not published in English were excluded. Much of the advice is based on expert opinion and practice because of a lack of other evidence. The system used to grade the evidence and guidance recommendations is that published by the US Department of Health and Human Services Agency for Healthcare Policy and Research (AHCPR)<sup>5</sup> These are indicated in bold type throughout the text e.g. **Ib** (see appendix 1).

Review is planned in 3 years, and forms part of the work undertaken by the Clinical Effectiveness Group (CEG) for BASHH (British Association for Sexual Health and HIV).

## Box 1 Summary of key recommendations

### When to consider testing for HIV

- Any patient presenting to a GUM clinic should be offered an HIV test regardless of signs or symptoms of disease or risk factors for infection. **III B**
- It is recommended that patients have a baseline HIV test done at presentation and if necessary this be repeated at 3 months from the time of any risk activity. **IIb B**
- People exposed to the risk of HIV should not be fully reassured until at least 3 months have passed during which they remain sero-negative (the window period). **IV C**

### How to test for HIV

Please refer to the Health Protection Agency (HPA) laboratory testing guidelines (as prepared by the HIV Laboratory Diagnoses Forum) for comprehensive details on the testing recommendations and methodology.

- Screening for HIV infection on venous blood is recommended. **IIa B**
- A properly validated confirmatory testing algorithm must be used to confirm HIV infection. **IV C**
- All patients whose first specimen indicates evidence of HIV infection must have their HIV status confirmed by tests on a second sample collected at another time. **IV C**

### Pre-test discussion, informed consent and confidentiality

- Testing should be undertaken only with the individual's specific informed verbal consent which should be documented. **IV C**
- Patients must be given a clear indication why testing is being considered. **IV C**
- Provision of a leaflet about HIV testing can provide much of the information needed prior to obtaining consent. **III B**
- Patients identified as being at high risk for HIV or those with particular concerns should be offered more in depth discussion or counselling in addition to a test. **IV C**
- Pre test discussion (PTD) is appropriate for the majority of patients being tested with the aim of obtaining informed verbal consent. **IV C**

### Methods to increase the uptake of testing

- An information leaflet should be used to increase uptake of HIV antibody testing. **III B**
- All patients attending GUM clinics should be offered an HIV test on an 'opt-out' basis. **IIIb B**
- HIV prompts in case notes. **IV C**

### Methods of giving results

- It essential that procedures are established for how the patient will receive the result, with particular attention to the means by which a positive result will be delivered. **IV C**
- Arrangements for communicating the results should be discussed and agreed with the patient at the time of testing. **IV C**

## When to consider testing for HIV

### Recommendations

- Any patient presenting to a GUM clinic should be offered an HIV test regardless of signs or symptoms of disease or risk factors for infection. **III B**
- It is recommended that patients have a baseline HIV test done at presentation and if necessary this be repeated at 3 months from the time of any risk activity. **IIb B**
- People exposed to the risk of HIV should not be fully reassured until at least 3 months have passed during which they remain sero-negative (the window period). **IV C**

The benefits from knowing the diagnosis, and thus being able to act on this, has clearly been shown to improve the life expectancy of the individual and may outweigh many other issues <sup>6</sup>.

Improved antibody tests and the application of PCR tests have served to lessen the interval it takes to detect infection (in some cases less than 2 weeks from exposure). Patients asked to return 3 months after suspected high risk activity for HIV transmission often fail to do so <sup>7</sup>. Thus, testing of individuals should not be delayed for 3 months, particularly in those suspected of infection: those unwell or who may be seroconverting. **IIb B**

Observational data are limited <sup>8-14</sup>, but in ten years of application of the 'three months rule' by all members of the UK HIV Laboratory Forum no reports of its failure have been received, and thus it is recommended that in general the three month rule continues to be applied <sup>15</sup>. **IV C** Patients may be infectious to others during this period and should be advised of this. In cases where post exposure prophylaxis (PEP) is given a 6 month follow-up test is recommended due to the fact that antiretrovirals may reduce replication and prolong antibody response <sup>15</sup>.

The presence of clinical features suggesting HIV infection (see box 2) or a particular increased risk should be noted (see box 3). Consideration should be given to ask such individuals to return to the clinic for the result, providing if necessary the opportunity of additional support and counselling. Those who exhibit clinical symptoms may also require medical input prior to the result of the HIV test.

**Box 2**

## Clinical features suggesting HIV infection

- Suspected primary infection with a seroconversion illness
- Any unusual manifestation of bacterial, fungal or viral disease:
  - infection with tuberculosis; suspected *Pneumocystis jiroveci* (previously *Pneumocystis carinii*) pneumonia; or suspected cerebral toxoplasmosis
  - oral/oesophageal candidiasis or hairy leucoplakia
- Persistent genital ulceration
- Unusual Tumours e.g. cerebral lymphoma, non-Hodgkin's lymphoma or Kaposi's sarcoma
- Unexplained thrombocytopenia or lymphopenia
- Unusual skin problems such:
  - severe seborrheic dermatitis, psoriasis or molluscum contagiosum
  - re-occurring herpes zoster or herpes zoster in a young person
- Persistent generalised lymphadenopathy or unexplained lymphoedema
- Neurological problems including peripheral neuropathy or focal signs due to a space occupying intra cerebral lesion
- Unexplained weight loss or diarrhoea; night sweats; or pyrexia of unknown origin

## How to test for HIV

### Recommendations

For greater detail please refer to the Health Protection Agency (HPA) laboratory testing guidelines (as prepared by the HIV Laboratory Diagnoses Forum) for comprehensive details on the testing recommendations and methodology<sup>16</sup>.

- Screening for HIV infection on venous blood is recommended. **IIa B**
- A properly validated confirmatory testing algorithm must be used to confirm HIV infection. **IV C**
- All patients whose first specimen indicates evidence of HIV infection must have their HIV status confirmed by tests on a second sample collected at another time. **IV C**

### Current Screening Tests

Ideally, an HIV antibody test should be performed on venous blood<sup>15-16</sup>. **IIa B** Many laboratories have been employing fourth generation HIV screening tests. They detect anti-HIV (nearly all are capable of detecting all three main Ig classes: IgM, IgG and IgA) and p24 antigen. The proven appearance of HIV antibody or antigen in a patient previously known to be sero-negative is evidence of HIV infection. All patients whose first specimen indicates evidence of HIV infection must have their HIV status confirmed by tests on a second sample collected at another time. **IV C** Patients providing a specimen reactive in the screening assay, but not confirmed to be consistent with HIV infection, should be retested using a fresh blood specimen collected at least 14 days later. **IV C** In order to confirm infection laboratories should have in place a properly validated confirmatory algorithm, and a mechanism to refer on specimens giving atypical findings<sup>16</sup>. **IV C**

Laboratories undertaking HIV testing should participate in the National Quality External Assessment Service (NEQAS) quality assurance programme and should preferably have Clinical Pathology Accreditation (CPA). **IV C**

Detection of the virus using polymerase chain reaction (PCR) during the window period is possible, and evidence suggests that an infection may often be detected 7 -10 days earlier than when using a 4<sup>th</sup> generation EIA screening test. However, it should be borne in mind that false positive tests occasionally occur and also that the test is not licensed for this application<sup>17</sup>.

In oral fluid samples conversion to antibody positivity may take longer. A single study indicated the window may be extended for a further two weeks<sup>18</sup>, though the exact period will depend on which serum and oral fluid tests are being compared. Thus, 16 weeks from the time of exposure should be allowed for if they are being used to exclude infection. All HIV screening tests should carry a CE mark. There are currently none available within the UK (although this position may change). Generally oral fluid testing should be avoided unless venepuncture is difficult or not possible<sup>15</sup>. **IV C**

## **Pre-test discussion, informed consent and confidentiality**

### Recommendations

- Ordinarily testing should be undertaken only with the individual's specific informed verbal consent which should be documented. **IV C**
- Patients must be given a clear indication why testing is being considered. **IV C**
- Provision of a leaflet about HIV testing can provide or replace much of the information needed prior to obtaining consent. **III B**
- Patients identified as being at high risk for HIV or those with particular concerns should be offered more in depth discussion or counselling in addition to a test (see box 3). **IV C**
- Pre test discussion (PTD) is appropriate for the majority of patients being tested with the aim of obtaining informed verbal consent. **IV C**

The term "pre-test counselling" has been used in the past to describe a person needing to see a professional with specific training and expertise in relation to HIV and/or counselling prior to undertaking an HIV test. Today the term "pre-test discussion" (PTD) is more appropriate. Its primary purpose is to establish informed consent for the HIV test, which means the individual must be competent to consent. They should understand the purpose, risks and benefits of being tested and of not being tested (see box 4), and they must give their consent voluntarily.

HIV testing is now considered part of routine sexually transmitted infection (STI) screening. However, more in depth pre-test discussion should be available for those requiring or requesting it or those at high risk of a positive result (see box 3). It is at this time you may want to explore support and coping mechanisms of receiving a positive result.

Although much of the information required to be given prior to informed consent can be delivered verbally, it can be aided by a leaflet<sup>20</sup>. However, it remains essential to ensure that the individual understands the information given and that consent to testing is obtained. Verbal consent is sufficient and this should be documented in the medical

records.

### Testing without consent

It is most exceptional for a patient to be tested without their consent. This is discussed in General Medical Council (GMC) guidance<sup>19</sup> (see appendix 2 for summary). If it is thought that an unconscious patient may have an HIV related illness then testing without their consent might be justifiable if the matter were urgent and deemed in the best interests of the patient. Once they regain consciousness then the patient should be told that they have been tested, the reason for doing so and the result. Their result should not be passed on to anyone not involved in their care e.g. a relative without their permission. In all cases the doctor must be able to justify their actions and must take into consideration recent medical advances, consensus opinion and guidance from professional bodies.

### Testing after possible occupational exposure to HIV

If a healthcare professional suffers a significant sharps injury involving exposure to a patient's blood, informed consent must be obtained from the patient before testing for HIV (and is usually granted). The guidance from the Expert Advisory Group on AIDS<sup>21</sup> gives further detailed information on this subject and should be referred to.

When considering testing patients who are unconscious at the time the healthcare worker sustains a sharps injury, in addition, the relevant guidance from the General Medical Council (GMC) should be consulted, together with advice from an experienced colleague<sup>19</sup>. **IV C**

### Confidentiality

Patients should be informed that their confidentiality will be protected according to GMC guidance<sup>19</sup>. In addition, confidentiality of positive results should be respected according to common law, Sexually Transmitted Infection (STI) regulations, Department of Health (DoH) guidance and the Data Protection Act. Only in exceptional circumstances can confidentiality be breached e.g. infected healthcare worker continuing to undertake exposure prone procedures or seizure of medical records by court order. Consequently, patients should also be advised that confidentiality is not absolute and that doctors may be legally bound to disclose HIV status information. Individual services may decide to include this information as part of their pre-test discussion or as part of their leaflet.

Consent should normally be obtained from an HIV infected patient prior to disclosure of their status to their General Practitioner (GP). Patients

should be encouraged to have their GP involved in their care.

Partner disclosure is still evolving in case law and legal advice from a defence organisation may be needed in cases where partner notification without consent of the patient may become an issue.

**Box 3**

Groups who may require more in depth discussion are:

- Those at high risk of HIV infection
  - men who have sex with men
  - injecting drug users
  - people from countries with a high prevalence of HIV infection e.g. sub-Saharan Africa, Caribbean, SE Asia
  - sexual partners of the above
  - Presence of another blood borne or sexually transmitted infection, e.g. syphilis, hepatitis B, C.
- Patients with a psychiatric history/ high level of anxiety/ sexual or relationship issues
- Rape/ sexual assault victims
- Those with occupational issues e.g. who currently or who may in the future perform exposure prone procedures
- Those involved in commercial sex work.

**Box 4**

Areas to be covered in pre test discussion are:

- The benefits of testing
  - The health benefits of current treatments
  - Knowing HIV status can allay anxiety
  - A positive test may motivate people to reduce risk activities
  - The opportunity to reduce the risk of transmission of the infection to others e.g. infants, sexual partners
- A risk assessment, including date of last risk activity
- The 'window period'
- Implications of testing for mortgages, insurance, occupational risks, and confidentiality
- Details of how the result will be given
- Where appropriate to explore support and coping mechanisms
- Obtaining informed consent for the test
- Information about HIV transmission and risk reduction as necessary

## Insurance issues

Patients should be reassured that a negative HIV test result, or the fact of having had a HIV test, should not affect an individual's future applications for insurance<sup>22</sup>. Patients should be informed that a positive result would affect their ability to get life insurance, mortgages and other financial services and products (see appendix 3 for more details).

## Methods to increase the uptake of testing

### Recommendations

- An information leaflet should be used to increase uptake of HIV antibody testing. **III b B**
- All patients attending GUM clinics should be offered an HIV test on an 'opt-out' basis. **III b B**
- HIV 'prompts' in case notes. **IV C**

A number of studies have examined the methods of increasing uptake of HIV testing. The provision of an information leaflet<sup>20</sup> and the combination of this with the offer of HIV 'as a routine test' has significantly increased uptake<sup>20, 23-26</sup>. Staff training is important and a series of 'HIV prompts' on sexual history sheets was offered in one clinic<sup>27</sup>.

Whilst all of these methods reported a rise in the number undergoing testing, limited analysis by risk group was undertaken in any of the studies. In addition, there was absence of randomisation (by patient, or setting) and of time-matched control groups.

Amongst antenatal clinic attenders 'opt-out' programmes have generally recorded significantly higher uptake of testing<sup>28-29</sup>, and levels of anxiety regarding HIV testing have fallen<sup>26</sup>. Opt-out initiatives have also been used in GUM settings to increase uptake of HIV testing<sup>25,30</sup>.

## Methods of giving results

### Recommendations

- It essential that procedures are established for how the patient will receive the result, with particular attention to the means by which a positive result will be delivered. **IV C**
- Arrangements for communicating the results should be discussed and agreed with the patient at the time of testing. **IV C**

### Face-to-face

Face-to-face provision of HIV test results is strongly encouraged for

- ward based patients
- patients likely to be positive
- those with mental health issues or risk of suicide
- those for whom English is a second language
- young people under 16
- those who may be highly anxious or vulnerable

### Providing Test Results by Telephone or Text

Providing low risk patients the option of receiving HIV test results by telephone or text is now widely practiced in GUM settings<sup>31</sup>. If it is to be undertaken then a protocol for doing so should be in place. **IV C** In some GUM clinics patients are told they will only be contacted if a test result is positive, usually in the context where other tests have also been performed.

### Written results

There may be occasions when patients request or require written confirmation of their results. A written protocol is recommended to set out criteria for those who receive results in this way, and how this is done. It is preferable to have a written letter signed by the doctor (or another appropriate health care professional), rather than a copy of the actual result, and this should be addressed to a specific individual, not 'to whom it may concern'. This should be documented in the notes along with any relevant discussion, and copies of any letters. Photographic identification e.g. passport should be brought along by patients requesting written confirmation and the identification used (e.g. passport number) included on the letter.

### Need for post-test discussion for individuals who are negative

Although there is limited evidence to suggest that individuals need post-test discussion, there are some patients who may benefit from further counselling or discussion around risks and behaviour change. Information on the need for a re-test if still within the window period can also be discussed.

### Non attendance for positive results

It is recommended to have an agreed process following failure of a patient to return for a positive result. It may be the patient's responsibility to get the result, but the clinic also has a responsibility of care towards the patient. If there is a means of contacting the patient

every attempt should be made to establish contact with him/her (in some cases this may be through the GP), and any communications documented in the case notes. It may be necessary to discuss the matter with other or senior colleagues and possibly the local consultant in public health (this may be done on an anonymous basis). The outcome of these discussions should be documented in the notes and any rationale for subsequent action (or inaction) made clear and justifiable.

### Health promotion information

It is considered good practice to offer health promotion advice to those at continued risk of infection or on-going transmission. However, it is beyond the remit of this guideline to offer formal recommendations on this.

### **Auditable outcome measures**

The National Strategy for Sexual Health and HIV<sup>2</sup> has set HIV testing targets for GUM services: to offer HIV testing to all GUM clinic attendees by the end of 2004 with a view to increasing the uptake to those offered it to 40% by the end of 2004 and to 60% by the end of 2007. By the end of 2007 it is hoped that the number of previously undiagnosed HIV positive people attending clinics is reduced by 50%.

- Each new patient attending a GUM service for the investigation or management of a STI should be offered HIV antibody testing, unless known to be HIV seropositive.
- Uptake of HIV antibody testing should be 60% of such new patients.
- Of patients found to be HIV positive, 100% should be informed of their test result.

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### **Editorial Independence**

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### **REFERENCES**

1. The UK Collaborative group for HIV and STI Surveillance. Mapping the Issues. HIV and other sexually transmitted infections in the UK in 2005. London: Health Protection Agency Centre for Infections. 2005
2. The national strategy for sexual health and HIV; July 2001: [www.doh.gov.uk](http://www.doh.gov.uk).
3. A Thomas, G Forster, A Robinson, K Rogstad. National guideline for the management of suspected sexually transmitted infections in children and young people. Arch Dis Child. 2003 Apr;88 (4):303-11.
4. Rogstad K, Palfreeman A HIV testing for patients attending general medical services: concise guidelines. Clin Med. 2004 Mar-Apr;4(2):136-9.
5. US Department of Health and Human Services Agency for Healthcare Policy and Research. [www.ahrq.gov](http://www.ahrq.gov).

6. British HIV Association (BHIVA) Guidelines for the Treatment of HIV-Infected Adults with Antiretroviral Therapy. *HIV medicine* 2003 Vol 4 (Supplement 1), 1-41.
7. Munday P, Mullan H. Encouraging HIV testing in GUM clinics - can we dispense with the pre-test discussion? *International Journal of STD & AIDS* 1999;10:728-729.
8. Busch MP, Statten GA. Time course of viremia and antibody seroconversion following human immunodeficiency virus exposure. *Am J Med*, 1997; 102: 117-124.
9. Pinto LA, Landay AL, Berzofsky JA, Kessler HA, Shearer GM. Immune response to human immunodeficiency virus (HIV) in healthcare workers occupationally exposed to HIV-contaminated blood. *Am J Med*, 1997; 102(5B): 21-24.
10. Lindback S, Thorstensson R, Karlsson AC, von Sydow M, Flamholz L, Blaxhult A et al. Diagnosis of primary HIV-1 infection and duration of follow-up after HIV exposure. Karolinska Institute Primary HIV Infection Study Group. *AIDS*, 2000; 14(15): 2333-9.
11. Phair JP, Margolick JB, Jacobson LP, Phillips J, Rinaldo C, Kaslow R, et al. Detection of infection with human immunodeficiency virus type 1 before seroconversion: correlation with clinical symptoms and outcome. *J Infect Dis*, 1997; 175(4): 959-62.
12. Groopman JE, Caiazzo T, Thomas MA, Ferriani RA, Saltzman S, Moon M et al. Lack of evidence of prolonged human immunodeficiency virus infection before antibody seroconversion. *Blood*, 1988; 71(6): 1752-4.
13. Henrard DR. Virological and immunologic characterization of symptomatic and asymptomatic primary HIV-1 infection. *J Acquir Immune Defic Syndr Hum Retrovirol*, 1995; 9(3): 305-10.
14. Ciesielski CA, Metler RP. Duration of time between exposure and seroconversion in healthcare workers with occupationally acquired infection with human immunodeficiency virus. *Am J Med*, 1997; 102(5B): 115-6.
15. Smit EJ. Screening guidelines for sexually transmitted Infections: Human Immunodeficiency Virus (HIV). [www.BASHH.org.uk](http://www.BASHH.org.uk).
16. Parry JV, Mortimer PP, Perry KR, Pillay D, Zuckerman M, for the Health Protection Agency HIV Laboratory Diagnoses Forum. Towards error-free HIV diagnosis: guidelines on laboratory practice *Commun Dis Public Health* 2003; 6(4): 334-50
17. Brambilla D, Granger S, Jennings C, Bremer J. Rates of False-Positive results on quantitative HIV RNA Assays. Abstract 236: CROI 2001
18. Gallo D, George JR, Fitchen JH, Goldstein AS, Hindahl MS. Evaluation of a system using oral mucosal transudate for HIV-1 antibody screening and confirmatory testing. Orasure Clinical Trials Group. *JAMA* 1997 March 12; 227(10):792
19. Serious Communicable Diseases, General Medical Council 1997 [www.gmc-uk.org](http://www.gmc-uk.org).

20. Rogstad K, Bramham L, Lowbury R, Kinghorn G. The use of a leaflet to replace verbal pre-test discussion for HIV - effects and acceptability. *Sex Transm Infect.* 2003 Jun;79(3):243-5.
21. HIV Post exposure prophylaxis - Guidance from the UK Expert Advisory Group on AIDS: UK Health Department. July 2000 [www.doh.gov.uk/eaga:/publications.htm](http://www.doh.gov.uk/eaga:/publications.htm):
22. ABI Statement of best practice on HIV and Insurance: Association of British Insurers. October 2004. [www.abi.org.uk](http://www.abi.org.uk)
23. Simpson WM, Johnstone FD, Boyd FM, Goldberg DJ, Hart GJ, Prescott RJ. Uptake and acceptability of antenatal HIV testing: randomised controlled trial of different methods of offering the test. *BMJ* 1998;316(7127):262-267.
24. Read J, Wincelous S J. New strategies for increasing the detection of HIV: analysis of routine data. *BMJ* 2003;326:1066-7
25. Stanley B, Fraser J, Cox N "Uptake of HIV screening in Genitourinary Medicine after change to opt-out consent" *BMJ* 2003: 326; 1174
26. Simpson WM, Johnstone FD, Goldberg DJ, Gormley SM, Hart GJ. Antenatal HIV testing: assessment of a routine voluntary approach. *BMJ* 1999;318(7199):1660-1661.
27. Lister P, Thirlby D, Fox E. Identifying HIV risk and increasing HIV testing within routine GUM consultation. MSSVD Spring Conference; 2002; Oslo
28. Simpson W, Johnstone FD, Hart GJ, Goldberg DJ, Boyd FM. A comparison of opt-in and opt-out HIV testing in antenatal care: uptake and acceptability in Edinburgh, Scotland. XII International Conference on AIDS; 1998; Geneva.
29. Jayaraman GC, Preiksaitis JK, Larke B. Mandatory reporting of HIV infection and opt-out prenatal screening for HIV infection: effect on testing rates. *CMAJ.* 2003 Mar 18;168(6):679-82.
30. Day S, Lakhani D, Hankins M, Rodgers CA. Improving uptake of HIV testing in patients with a confirmed STI. *Int J STD AIDS.* 2004 Sep;15(9):626-8.
31. S Kegg M Natha R Lau M Pakianathan Communication with patients: are email and Text the answer P147 BASHH/ASTDA Bath 2004 *Int J STD and AIDS* 2004 Vol 15 (Suppl 1):46

## Appendix 1

### Levels and grading of evidence

#### Table A

Level Type of evidence

Ia Evidence obtained from meta-analysis of randomized controlled trials

Ib Evidence obtained from at least one randomized controlled trial

IIa Evidence obtained from at least one well-designed controlled study without randomization

IIb Evidence obtained from at least one type of well-designed quasi-experimental study

III Evidence obtained from well-designed, non-experimental descriptive studies, such as comparative studies, correlation

studies and case control studies

IV Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

**Table B**

Grade Recommendation

A

(Evidence levels Ia, Ib)

Requires at least one randomized controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation

B

(Evidence levels IIa, IIb, III)

Requires availability of well conducted clinical studies but no randomized clinical trials on the topic of recommendation

C

(Evidence level IV)

Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable studies of good quality

**Appendix 2****Summary of General Medical Council consent to testing for a serious communicable disease**

You must obtain consent from patients before testing for a serious communicable disease, except in the rare circumstances described below.

**Children**

Where a child cannot give or withhold consent, you should seek consent from a person with parental responsibility for the child. If you believe that that person's judgement is distorted, for example, because he or she may be the cause of the child's infection, you must decide whether the medical interests of the child override the wishes of those with parental responsibility. Whenever possible you should discuss the issues with an experienced colleague before making a decision. If you test a child without obtaining consent, you must be prepared to justify that decision.

**Unconscious patients**

You may test unconscious patients for serious communicable diseases, without their prior consent, where testing would be in their immediate clinical interests. You should not test unconscious patients for other purposes.

**Injuries to health care workers**

If you or another health care worker has suffered a needle stick injury or other occupational exposure to blood or body fluids and you consider it necessary to test the patient for a serious communicable disease, the patient's consent should be obtained before the test is undertaken. If the patient is unconscious when the injury occurs consent should be sought once the patient has regained full consciousness. If appropriate, the injured person can take prophylactic treatment until consent has been obtained and the test result is known.

If the patient refuses testing, is unable to give or withhold consent because of mental illness or disability, or does not regain full consciousness within 48 hours, you should reconsider the severity of risk to yourself, or another injured health care worker, or to others. You should not arrange testing against the patient's wishes or without consent other than in exceptional circumstances, for example where you have good reason to think that the patient may have a condition such as

HIV for which prophylactic treatment is available. In such cases you may test an existing blood sample, taken for other purposes, but you should consult an experienced colleague first. It is possible that a decision to test an existing blood without consent could be challenged in the courts, or be the subject of a complaint to your employer or the GMC. You must therefore be prepared to justify your decision.

If you decide to test without consent, you must inform the patient of your decision at the earliest opportunity. In such cases confidentiality is paramount: only the patient and those who have been exposed to infection may be told about the test and its result. In these exceptional circumstances neither the fact that test has been undertaken, nor its result, should be entered in the patient's personal medical record without the patient's consent.

If the patient dies you may test for a serious communicable disease if you have good reason to think that the patient may have been infected, and a health care worker has been exposed to the patient's blood or other body fluid. You should usually seek the agreement of a relative before testing.

## Appendix 3

### **Insurance issues**

#### ***Implications of a negative HIV test***

A negative HIV test result, or the fact of having had an HIV test, should not affect an individual's future applications for insurance<sup>1</sup>.

Until the mid-1990s insurance companies frequently asked applicants for insurance if they had ever had an HIV test (even if negative), as this was seen as an indicator of higher risk for HIV and therefore relevant for actuarial decision-making. At that time, insurance implications were a significant reason for individuals to choose not to test.

In 1994, the Association of British Insurers (ABI) issued a statement of practice for its member companies, recommending that no questions should be asked of applicants for life insurance about negative HIV tests or previous HIV test counselling. This has led to a change in practice, as ABI members are bound by the statement. (A small percentage of insurers do not have ABI membership and the statement has no legal status, so variations in practice are still theoretically possible.) It is likely that the ABI statement, plus the increasing incentive to test presented by highly active antiretroviral therapy (HAART), have made insurance implications a less important consideration for individuals thinking about taking a test. The ABI has issued a new statement of practice (to replace that of 1994) effective as of 30 September 2005. This reiterates its

position on questions about HIV tests, and offers recommendations on questions to assess HIV risk<sup>1</sup>.

### ***Implications of a positive HIV test***

#### *Cover under existing insurance policies*

A person with existing life insurance who is later diagnosed with HIV will usually be covered for an HIV-related claim (exclusions are relatively rare in life insurance policies). HIV related claims will often be excluded from some other types of insurance, such as critical illness and income protection – details of each policy need to be checked. The ABI advises that excluding claims which are for reasons other than HIV (e.g. unrelated heart attack in a critical illness policy) purely because someone has HIV would be unlawful<sup>2</sup>.

#### *Ability to get insurance*

Having HIV affects an individual's ability to get insurance related in any way to their health. Insurance companies have the following options when responding to applications from people with HIV, and the option chosen will largely depend on the type of insurance policy applied for:

- ◆ to refuse cover entirely,
- ◆ to offer cover but exclude HIV-related claims,
- ◆ to offer cover, inclusive of HIV-related claims, but apply restrictions (such as higher premiums, limited length of cover, and specified criteria for acceptance e.g. CD4 count and viral load currently available from one company ).

Life insurance and endowment policies will be refused. (This approach is currently under discussion in the light of better health outcomes from HAART and should be kept under review for these guidelines.) A person with HIV wishing to apply for a mortgage should consider applying for a repayment mortgage.

#### *Travel Insurance*

Most off-the-peg travel insurance policies exclude cover for pre-existing medical conditions, including HIV.

A small number of travel insurance policies offer cover for such conditions. Details of these are available from the Terrence Higgins Trust Helpline or the National AIDS Manual. One travel insurance policy has been developed by the National AIDS Trust in partnership with two members of the insurance industry, specifically to meet the needs of people with HIV. Acceptance for cover, and cost of premium, depend on medical assessment.

#### *Disclosing HIV status when applying*

A person who knows they have HIV but does not disclose this when applying for life or health-related insurance is failing to disclose a material fact. Such a failure could render the entire policy invalid.

### *GP reports*

Insurance companies usually ask the GP of an individual applying for life or permanent health insurance (income protection) for a medical report, with their patient's consent, particularly if they have declared a medical condition on their application form. Refusal to consent to the GP giving a report will normally result in cover being refused. The GP will be required to state if their patient has had a positive HIV test or is awaiting an HIV test result. GPs are not asked to speculate about the patient's lifestyle on the new version of the general practitioner's report. The BMA advises GPs not to answer such lifestyle questions<sup>3</sup>. GPs should not be asked if a patient has had a negative HIV test or counselling for an HIV test.

GMC guidance (2004) on confidentiality emphasises the need to obtain fully informed patient consent for medical reports for a third party<sup>4</sup>. The consent wording agreed with the BMA has now been amended and expanded to ensure that all patients are aware of the information GPs are asked to disclose to insurers<sup>5</sup>. The GMC guidance suggests that GPs show the form to patients before completion, to ensure their understanding of its scope. Life insurance application forms must still offer applicants the option of seeing their GP's completed report before it is returned to the insurance company.

More detailed information about medical reports for insurance can be found in the joint ABI/BMA guidelines<sup>6</sup>. A standard GP report form, patient consent form and covering letter to GPs have been jointly produced by the BMA and ABI<sup>5</sup>.

### *HIV testing for insurance applications*

In some cases, insurers may require an HIV test as part of medical assessment for individuals applying for insurance. This usually occurs if the policy is of a high value or if the individual has been identified, through details in their application or their GP's report, as being at higher risk of HIV infection. The applicant may be offered the option of arranging the test through their own doctor or through one nominated by the insurance company, but GPs are not obliged to perform HIV tests for insurance purposes for their registered patients. If they do so they should, as with all tests, make sure the patient has sufficient information and has given consent.

*Public and professional awareness and attitudes*

Those accessing testing may prefer to choose GUM as the location for requesting an HIV test because they do not wish to consult their GP because of concerns about confidentiality, including life insurance implications<sup>7-9</sup>.

GPs may choose not to record referrals to GUM for HIV testing because of life insurance considerations, and many GPs still believe that a negative HIV test can adversely affect life insurance applications (10).

1. Association of British Insurers. Statement of best practice on HIV and insurance. London:ABI, October 2004. Available at: [www.abi.org.uk](http://www.abi.org.uk)
2. Association of British Insurers. A life and disability insurer's guide to the Disability Discrimination Act 1995. London:ABI,2001. Available at [www.abi.org.uk/members/industrybrief/abikey/disabled/LifeAndDisability.pdf](http://www.abi.org.uk/members/industrybrief/abikey/disabled/LifeAndDisability.pdf)
3. British Medical Association Ethics Department. Medical ethics today. The BMA's Handbook of ethics and law. 2<sup>nd</sup> edn. London: BMJ Books, 2004
4. General Medical Council . Confidentiality: Protecting and Providing Information. London: GMC, 2004
5. BMA/ABI. The GP insurance package. London: October 2003. Available at: [www.bma.org.uk/ap.nsf/Content/GPR](http://www.bma.org.uk/ap.nsf/Content/GPR)
6. Association of British Insurers and British Medical Association. Medical information and insurance. Joint guidelines from the British Medical Association and the Association of British Insurers. London: BMA, 2002. [www.bma.org.uk/ap.nsf/Content/MedicalInfoInsurance](http://www.bma.org.uk/ap.nsf/Content/MedicalInfoInsurance))
7. Webb D. Defining Quality – Gay Men's Values in Primary Care. Southampton: The Wessex Institute for Health Research and Development, University of Southampton, 1999.
8. Madge S, Jones M, Mocroft A et al. Do people attending a same day testing clinic discuss their need for a HIV test with their GP? *Br J Gen Practice*, 1999, 49, 813-815.
9. Keane FE, Young SM. GPs, STDs and life insurance. *International Journal of STD and AIDS*. 5(5):318-21; discussion 322-6, 1994 Sept-Oct.
10. Whittet S, Trail P, de Ruiter A et al. General practitioners' attitudes and beliefs on antenatal testing for HIV: postal questionnaire survey. *BMJ* 2000; 321:934