

*From the Chief Medical Officer*  
Dr Michael McBride



Department of  
**Health, Social Services  
and Public Safety**

[www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)

HSS(MD)34/2008

AN ROINN

**Sláinte, Seirbhísí Sóisialta  
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydènter Heisin  
an Fowk Siccar**

Castle Buildings  
Stormont Estate  
Belfast BT4 3SQ  
Tel: 028 9052 0563  
Fax: 028 9052 0574  
Email: [michael.mcbride@dhsspsni.gov.uk](mailto:michael.mcbride@dhsspsni.gov.uk)

To: Chief Executives HSC Trusts  
Chief Executives HSS Boards  
Chief Executive Health Promotion Agency  
All Doctors in Northern Ireland  
All Nurses in Northern Ireland  
All Pharmacists in Northern Ireland  
Directors of Public Health (for onward dissemination  
to Sexual Health Teams)  
Head of School of Nursing and Midwifery, QUB  
Head of School of Nursing, UU  
NI Centre for Pharmacy Learning & Development,  
QUB  
Dean of QUB Medical School  
Postgraduate Dean, NIMDTA

Your Ref:  
Our Ref: HSS(MD)34/2008  
Date: 20 October 2008

Dear Colleague

## **UPDATED GUIDANCE ON HIV – INCLUDING HIV TESTING, MANAGEMENT OF HIV INFECTION AND POST-EXPOSURE PROPHYLAXIS**

We are writing to draw your attention to a number of key documents which provide guidance in the areas of testing for HIV infection, management of HIV infection and post-exposure prophylaxis after HIV exposure. Full copies of these guidelines are attached as pdf documents to this letter and in addition are available on the websites of Medical Association for Sexual Health, [www.medfash.org.uk](http://www.medfash.org.uk) and the British HIV Association [www.bhiva.org](http://www.bhiva.org) and the Department's website [www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk). The three sets of guidance include:

1. **UK National Guidelines for HIV Testing 2008** which has been prepared by the British HIV Association, British Association of Sexual Health and HIV and the British Infection Society. They outline the procedures to be followed when testing for HIV and includes the recommendation that patients should be offered and encouraged to accept HIV testing in a wider range of settings that is currently the case. The DHSSPS Guidance of 2007 refers <http://www.dhsspsni.gov.uk/hss-md-19-2007.pdf>. Patients with specific indicator conditions should be routinely

recommended to have an HIV test. All doctors, nurses and midwives should be able to obtain informed consent for HIV testing the same way that they currently do for any other medical investigation.

We would ask you to implement these Guidelines as routine. A significant number of people in the UK remain unaware of HIV and thus remain at risk to their own health and passing their virus onto others. Late diagnosis is a very important factor associated with HIV related morbidity and mortality in the UK. As HIV is now a treatable medical condition, it is important that we ensure patients have access to advice and testing in all healthcare settings where appropriate.

2. The second set of Guidance which is attached to this letter entitled '**HIV for non-HIV Specialists, Diagnosing the Undiagnosed – A practical guide for healthcare professionals in secondary care to support improved detection and diagnosis of HIV in the UK**'. This Guidance aims to produce practical help and advice to raise awareness of HIV among non-HIV specialists, to reduce barriers to testing and to ensure that HIV testing becomes routine. The Guidance provides an overview of the common presenting conditions when generalists should consider a diagnosis of HIV and strategies for approaching the offer of an HIV test. These Guidelines compliment the above Guidance for carrying out HIV testing. Of note the full Guideline is available at the end of the booklet, you may wish to download this for your personal use.
3. The third publication which we would like to draw your attention to is the updated Guidance on HIV Post-Exposure Prophylaxis which has been produced by the UK Chief Medical Officers Expert Advisory Group on Aids (EAGA). It is available on the Department's website [http://www.dhsspsni.gov.uk/index/phealth/php/infectious\\_diseases/hiv.htm](http://www.dhsspsni.gov.uk/index/phealth/php/infectious_diseases/hiv.htm) and also on the Department of Health in England's website [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_088185](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_088185). This Guidance provides definitions on exposure to HIV and risk assessment process and action to be taken. It covers the exact post exposure prophylaxis to be prescribed in the context of HIV exposures and also the position of healthcare workers who are seconded overseas, including students on electives. This Guidance has already been shared with Trusts including Trust Pharmacy Departments.

The epidemiology of HIV infection in Northern Ireland is changing and we are currently seeing an increase in HIV infections in the Province. Information on the epidemiology of HIV is available on the website of the Communicable Disease Surveillance Centre NI at [www.cdscni.org.uk](http://www.cdscni.org.uk). As in previous communications on this



# **HIV post-exposure prophylaxis**

***Guidance from the UK***

***Chief Medical Officers' Expert***

***Advisory Group on AIDS***

## DH INFORMATION READER BOX

<b>Policy</b>	Estates
HR/Workforce	Performance
Management	IM & T
Planning	Finance
Clinical	Social Care/Partnership Working

<b>Document</b>	Best Practice Guidance
<b>Gateway Reference:</b>	10380
<b>Title</b>	HIV post-exposure prophylaxis: Guidance from the UK Chief Medical Officers' Expert Advisory Group on AIDS
<b>Author</b>	Department of Health
<b>Publication date</b>	19 September 2008
<b>Target audience</b>	PCT CEs, NHS Trust CEs, Foundation Trust CEs, Medical Directors, Directors of PH, Directors of Nursing, PCT PEC Chairs, Special HA CEs, Directors of HR, GPs, Emergency Care Leads, General Dental Practitioners, Accident and Emergency Departments, Heads of Midwifery, NHS Walk-in Centres, Consultants in Communicable Disease Control, GUM, HIV, Infectious Diseases, Virology, Microbiology, Occupational Medicine and Dental Public Health
<b>Circulation list</b>	
<b>Description</b>	Updated guidance on HIV post-exposure prophylaxis (PEP) following occupational exposure
<b>Cross reference</b>	N/A
<b>Superseded documents</b>	HIV post-exposure prophylaxis: Guidance from the UK Chief Medical Officers' Expert Advisory Group on AIDS (February 2004)
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<b>Timing</b>	N/A
<b>Contact details</b>	Gerry Robb Infectious Diseases and Blood Policy Room 531 Wellington House 133-155 Waterloo Road London SE1 8UG 020 7972 4430 gerry.robbs@dh.gsi.gov.uk www.dh.gov.uk/publications
<b>For recipient's use</b>	

# **HIV post-exposure prophylaxis**

***Guidance from the UK***

***Chief Medical Officers' Expert***

***Advisory Group on AIDS***

# Contents

<b>Chapter 1: Introduction</b>	<b>3</b>
1.1 Background and other sources of guidance	3
1.2 General principles	5
1.3 HIV and significant occupational exposure	7
1.4 Surveillance of occupational PEP usage	9
<b>Chapter 2: Risk assessment</b>	<b>11</b>
2.1 Immediate action	11
2.2 Circumstances of exposure	11
2.3 Assessment and testing of the source patient	12
2.4 Exposure to discarded needle/unknown source	15
<b>Chapter 3: PEP</b>	<b>17</b>
3.1 When to prescribe PEP	17
3.2 What to prescribe for PEP	18
3.3 Management of health care workers occupationally exposed to HIV: further issues, including follow-up	18
3.4 HIV seroconversion	24
3.5 Making PEP available: immediate access	25
3.6 Making PEP available: policies and protocols	26
<b>Chapter 4: UK health care workers seconded overseas including students on electives</b>	<b>32</b>
<b>Chapter 5: Exposure outside the hospital setting</b>	<b>36</b>
5.1 Equity of access and management	36
5.2 Other occupational groups	37
5.3 Children	37
5.4 Factors affecting use and efficacy of non-occupational PEP	38

<b>Annex A: Body fluids and materials which may pose a risk of HIV transmission if significant occupational exposure occurs</b>	<b>39</b>
<b>Annex B: General Medical Council guidance</b>	<b>40</b>
<i>Good Medical Practice</i> (2006)	40
<i>Serious Communicable Diseases</i> (1997)	40
Further information	41
<b>Annex C: What to prescribe for PEP</b>	<b>42</b>
Starter regimen	43
Side effects	44
<b>Annex D: Reporting of occupational exposures to HIV</b>	<b>47</b>
Reporting to HPA Centre for Infections (Cfi) or, in Scotland, to Health Protection Scotland (HPS)	47
Reporting of occupational exposure to HIV to the Health and Safety Executive (HSE)	48
Serious Untoward Incident reporting system	48
<b>Annex E: PEP: special circumstances</b>	<b>49</b>
Viral drug resistance	49
Pregnancy	50
<b>Annex F: Interactions of antiretroviral medications with commonly used medicinal products</b>	<b>52</b>
<b>Annex G: PEP for patients after possible exposure to an infected health care worker</b>	<b>53</b>
Blood exposure incidents	53
Assessment of incidents	55
Use of PEP	58
Follow-up of patients exposed to HIV-infected blood	59
Special considerations	59
<b>Annex H: Summary of evidence on maximum interval between exposure and commencing PEP</b>	<b>62</b>
<b>Annex I: EAGA PEP Working Group membership</b>	<b>64</b>
<b>References</b>	<b>66</b>



# Chapter 1: Introduction

## 1.1 Background and other sources of guidance

1. This document supersedes guidance on occupational HIV post-exposure prophylaxis (PEP) from the UK Chief Medical Officers' Expert Advisory Group on AIDS (EAGA) issued in February 2004 (1) and the interim update following the withdrawal of Viracept (nelfinavir) published in July 2007 (2). It should be read in conjunction with local needlestick injury policy.
2. The following sections have been clarified after reviewing the available evidence:
  - Maximum recommended interval between exposure and commencing PEP (paragraph 45).
  - Revised recommended schedule of serological investigations following occupational exposure to HIV, based on evidence from national surveillance of significant occupational exposures to blood-borne viruses, expert opinion and practicalities of application (Box 1, pages 21–23).
  - Recommended regimen for PEP starter packs (Annex C, paragraph 5).
3. Other significant amendments include:
  - Clarifying the implications of the Human Tissue Act 2004 and the Mental Capacity Act 2005 for testing incapacitated source (adult) patients for serious communicable diseases without consent (paragraph 32). and associated changes to Annex B.
  - A recommendation for good practice that all hospitals have the capacity to obtain an HIV test result (for source patient testing) ideally within 8 hours and not more than 24 hours after blood is taken (paragraph 34).

- The section on exposure outside the hospital setting has been shortened (Chapter 5). It cross-references guidance on PEP following sexual (non-occupational) exposure from the British Association for Sexual Health and HIV (BASHH) (3), which EAGA endorses. The BASHH guidance was reinforced by the Chief Medical Officer in a letter recommending PEP for sexual (non-occupational) exposure be made available as part of sexual health services in England (4).
  - Addition of a new Annex H summarising the evidence from animal and clinical studies on the maximum interval between exposure and commencing PEP.
4. Those responsible for occupational health provision to people in professions where there may be a risk of exposure to HIV-infected material outside health care settings (e.g. police, prison and fire service, voluntary aid agencies, armed forces) may wish to use these guidelines as a basis for developing guidance relevant to their own occupational setting. For example, advice to the Scottish Executive on guidance needed to protect front-line workers and victims of crime from blood-borne viral infections (5) refers to EAGA's guidance.
  5. Related guidance from the Advisory Committee on Dangerous Pathogens on *Protection against blood-borne infections in the workplace: HIV and hepatitis* (6) is currently undergoing revision. NHS Employers has issued the *Healthy workplaces handbook* (7) (<http://www.nhsemployers.org/practice/practice-2912.cfm>), which has replaced the *Blue Book (The management of health, safety and welfare issues for NHS staff)*.
  6. This document offers guidance on:
    - assessing the risk to a health care worker of acquiring HIV infection following occupational exposure;
    - when to recommend PEP;

- the choice of drugs;
- how to ensure that all health care workers have **immediate, 24-hour access** to advice on PEP, to drugs and to appropriate support;
- devising local PEP policies and protocols;
- appropriate support arrangements for health care workers seconded overseas, including medical students on 'electives';
- provision of PEP for exposures to HIV occurring outside the hospital setting;
- antiretroviral drug resistance;
- laboratory workers who may be exposed to unusual and/or highly resistant viruses;
- considerations about PEP for exposed women who are, or may be, pregnant;
- drug interactions; and
- PEP for patients after possible exposure to an infected health care worker.

## 1.2 General principles

7. In reviewing the guidance, EAGA's PEP Working Group (see Annex I) highlighted the following basic principles, which apply to the management of all exposures to HIV (i.e. occupational and non-occupational):
  - EAGA recommends the inclusion of local PEP policy guidance in induction programmes for new staff to educate and raise awareness among those at risk, including where to access PEP and the need for prompt attendance.
  - Timely provision of PEP (24-hour access).
  - Risk assessment.
  - Management and follow-up of all exposed individuals.

8. Occupational exposure to blood and body fluids potentially infected with HIV and other blood-borne viruses is unnecessarily common. Many exposures result from a failure to follow recommended procedures, including the safe handling and disposal of needles and syringes, or wearing personal protective eyewear where indicated.
9. Prevention of avoidable exposure is of prime importance. Adherence to the *Code of Practice for the Prevention and Control of Healthcare Associated Infections* (8), made under the Health Act 2006, which includes prevention of blood-borne virus infection, will serve to reduce the incidence of occupational exposures to a minimum.
10. This document concerns exposure to HIV and post-exposure prophylaxis. Any significant exposure to blood and some other body fluids or tissues (see Annex A) has the potential to transmit other blood-borne virus infections, such as hepatitis B (HBV) and hepatitis C (HCV). Therefore, an integrated approach to post-exposure management with respect to HIV, HBV and HCV is recommended.
11. There will remain occasions when exposure occurs despite careful attention to the correct procedures. If, despite measures being in place, exposure has occurred, it is a requirement under the Control of Substances Hazardous to Health (COSHH) Regulations 2002 to review the risk assessment (Reg 6(3)).
12. All health care workers in hospital and elsewhere (e.g. general medical and dental practitioners, community health care workers) should be informed and educated about the possible risks from occupational exposure and should be aware of the importance of seeking urgent advice following any needlestick injury or other occupational exposure (see paragraph 24). Training should ensure that everyone knows to whom to report (COSHH Reg 12). The guidance applies equally to students in health care settings.

13. Every NHS employer should have a policy on the management of exposures, which should specify the local arrangements for risk assessment, advice and the provision of PEP (8). This policy must ensure that adequate 24-hour cover is available and should designate one or more doctors who exposed persons may be referred to urgently for advice. Primary responsibility should lie with the occupational health service, with out-of-hours cover provided by Accident and Emergency (A&E) departments, unless there are other arrangements locally for out-of-hours cover to be provided by, for example, occupational health services. A&E departments would be expected to have access to on-call expert advice. Sources of such advice may include consultants in occupational health, HIV disease, genito-urinary medicine, virology, microbiology, infectious diseases and public health medicine. There should be clear channels for access to any necessary expert advice about HIV and PEP drugs.

### 1.3 HIV and significant occupational exposure

14. The risk of acquiring HIV infection following occupational exposure to HIV-infected blood is **low**. Epidemiological studies have indicated that the average risk for HIV transmission after percutaneous exposure to HIV-infected blood in health care settings is about 3 per 1,000 injuries. After a mucocutaneous exposure, the average risk is estimated at less than 1 in 1,000. It has been considered that there is no risk of HIV transmission where intact skin is exposed to HIV-infected blood.
15. A case–control study conducted by the US Centers for Disease Control and Prevention concluded that the administration of zidovudine prophylaxis to health care workers occupationally exposed to HIV was associated with an 81% reduction in the risk for occupationally acquired HIV infection (9). Four factors were associated with increased risk of occupationally acquired HIV infection:

- Deep injury.
  - Visible blood on the device which caused the injury.
  - Injury with a needle which had been placed in a source patient's artery or vein.
  - Terminal HIV-related illness in the source patient.<sup>1</sup>
16. It was estimated that the risk for HIV transmission after percutaneous exposures involving larger volumes of blood (i.e. where there was visible blood on the needle or in the syringe), particularly if the source patient's viral load was likely to be high, exceeds the average risk of 3 per 1,000.
  17. Information about primary HIV infection and evidence from animal models indicate that systemic viral dissemination does not occur immediately, leaving a window of opportunity during which post-exposure antiretroviral medication may be beneficial.
  18. In established HIV infection, combinations of antiretroviral drugs are more potent than zidovudine alone in suppressing viral replication. This, together with the rise in prevalence of antiretroviral drug resistance amongst HIV-infected individuals (10; 11), has led to the introduction of combination antiretroviral drug prophylaxis following occupational exposure to HIV.
  19. EAGA has considered the evidence for the efficacy of PEP with antiretroviral drugs and recommends that their use should be considered in certain circumstances. Other sources of information include reviews of antiretroviral PEP post-occupational exposure to HIV (12; 13), US guidelines (14) and their application in clinical practice (15), and consensus European guidelines (16).

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<sup>1</sup> Where the source patient is not on therapy and has uncontrolled viral load.

## 1.4 Surveillance of occupational PEP usage

20. The Health Protection Agency (HPA) has undertaken enhanced surveillance of significant occupational (percutaneous and mucocutaneous) exposure to blood-borne viruses (BBVs) in health care workers since 1997 (17). Around 200 centres in England, Wales and Northern Ireland participate (not full national coverage). Reporting is voluntary and only incidents involving exposure to a BBV-positive source, or where HIV PEP is initiated, are included. This provides current as well as historical data on PEP usage and HIV exposures. Initial reports from participating centres (mainly Occupational Health departments but also Genito-Urinary Medicine (GUM), Virology and Microbiology departments) are followed up at 6 weeks and 24 weeks and provide further information on the incident, testing of the source, what PEP was prescribed, reasons for discontinuation etc. Findings from this surveillance have informed revisions to the guidance.
21. Some of the key findings relating to occupational exposure to HIV, as reported to the scheme by October 2007, for incidents occurring in 2005–06 (HPA, unpublished data) are:
- Of the initial reports, 50% (482/956) involved exposures to hepatitis C and 25% (238/956) exposures to HIV. Overall, 29% (276/956) of reports involved HIV exposures, including to co-infected source patients.
  - Of those exposed to an HIV-positive source (including exposures to co-infected source patients), 57% (157/276) of health care workers commenced PEP following a percutaneous exposure and 24% (66/276) following mucocutaneous exposure. 18% (51/276) did not take PEP and for the remainder the PEP status was unknown (<1% (2/276)).
  - Where a time to commencing PEP was reported on the 6-week follow-up form, 38% (62/163) started PEP within an hour of exposure and 90% (147/163) overall

within 24 hours. Only 3% (5/163) were reported to have started PEP over 72 hours post-exposure.

- Where length of time on PEP was stated on the 6-week follow-up form, 17% (23/132) of health care workers exposed to an HIV-positive source discontinued all or part of their PEP regimen prematurely because of drug toxicity and 44% (8/18) of those exposed to a source of unknown status completed the 28-day course of PEP.
- In cases where PEP was initiated but the source was found to be negative, 52% (44/85) of health care workers had discontinued PEP within a day of initiating treatment, and 86% (73/85) overall had stopped within 7 days or fewer.
- Of 276 HIV-exposed health care workers originally reported to the scheme, 58% (161/276) were reported (on the 24-week follow-up form) to have undergone HIV post-exposure testing, with 46% (127/276) completing the recommended 24 weeks of follow-up.
- Five cases of HIV seroconversion in UK health care workers have been documented; four occurred in or before 1993, only one of whom received PEP (zidovudine monotherapy). The most recent case was in 1999, when seroconversion occurred despite combination PEP (18).

22. Locally conducted audits of occupational exposure to HIV and use of PEP have been reported (19; 20).



## Chapter 2: Risk assessment

### 2.1 Immediate action

23. Immediately following **any** exposure – whether or not the source is known to pose a risk of infection – the site of exposure, e.g. wound or non-intact skin, should be washed liberally with soap and water but without scrubbing. Antiseptics and skin washes should not be used – there is no evidence of their efficacy, and their effect on local defences is unknown. Free bleeding of puncture wounds should be encouraged gently but wounds should not be sucked. Exposed mucous membranes, including conjunctivae, should be irrigated copiously with water, before and after removing any contact lenses.
24. Prompt reporting of injuries is a necessary first step to enabling appropriate and rapid prescribing of PEP. A risk assessment needs to be made urgently by someone other than the exposed worker about the appropriateness of starting PEP, ideally an appropriately trained doctor designated according to local arrangements for the provision of urgent post-exposure advice. This guidance refers only to the issue of HIV post-exposure prophylaxis. Consideration should also be given to risk of exposure to hepatitis B and hepatitis C. An integrated approach to post-exposure management is provided in guidance from EAGA and the Advisory Group on Hepatitis (AGH) (21).

### 2.2 Circumstances of exposure

25. The issue of PEP should be considered after an exposure with the potential to transmit HIV, based on the type of body fluid or substance involved, and the route and severity of the exposure.
26. The designated doctor or other practitioner should first assess if the exposure reported by the health care worker

was **significant** – that is, with the potential to transmit HIV. There are three types of exposure in health care settings associated with significant risk. These are:

- (i) percutaneous injury (from needles, instruments, bone fragments, significant bites which break the skin etc);
- (ii) exposure of broken skin (abrasions, cuts, eczema etc);  
and
- (iii) exposure of mucous membranes including the eye.

(Note – the history and examination may highlight the need to institute other prophylactic and investigative regimens, e.g. antibiotic therapy, hepatitis B immunisation).

27. Some health care workers may have had occupational exposures which, after careful assessment, are not considered significant – i.e. they do not have the potential for HIV transmission. Such workers should be advised that the potential side effects and toxicity of taking PEP outweigh the negligible risk of transmission posed by the **type of exposure** because it is considered insignificant, whether or not the source patient is known or considered likely to be HIV infected.

### 2.3 Assessment and testing of the source patient

28. If initial assessment indicates that an exposure has been **significant** – that is, with the potential for HIV transmission – consideration should then be given to the HIV status of the source patient. It may be possible to ascertain from the medical record that a source patient has established HIV infection. Results from animal studies suggest that HIV PEP is most likely to be efficacious if started within the hour. An urgent preliminary risk assessment therefore should assess if it is appropriate to recommend taking the first dose of PEP. A more thorough risk assessment should be undertaken to inform a decision about whether to continue the regimen (see also paragraphs 39 and 40).

29. The designated doctor should ensure that appropriate arrangements are made to approach a source patient whose HIV status is not known and ask for their informed agreement to HIV testing. **This approach should not be undertaken by the exposed worker**, but may be made by another member of the clinical team responsible for the patient, subject to local arrangements. A universal approach to asking source patients to agree to have an HIV test avoids the need to make difficult judgements, simplifies and normalises the process and avoids potential discrimination against people perceived as belonging to groups associated with higher than average HIV prevalence.
30. When a source patient is asked to agree to undergo HIV testing, careful pre-test discussion will be needed, as will informed consent, which should include disclosure of the source patient's test result to the occupational health service and to the health care worker. This pre-test discussion can be provided by any appropriately trained and competent health care worker. Specialist pre-test discussion may sometimes be considered appropriate if the circumstances of the source patient are unusual or complex (e.g. source patient does not speak English, has mental health problems or a learning disability). For guidance on HIV testing, see references 22 and 23.
31. It is not considered acceptable to seek consent for source patient testing before surgery to guard against an exposure incident occurring during the procedure. Consent for testing should only be sought from the source patient after the exposure incident has occurred and its significance has been assessed. If there are practical obstacles to obtaining consent promptly (e.g. the patient is still under the influence of a general anaesthetic or has been discharged home), the decision to initiate PEP should be based on the available information. Ideally, patients at high risk of being infected with a blood-borne virus should be identified pre-operatively and offered testing on clinical grounds at that stage. This is

consistent with best practice for improving the detection and diagnosis of HIV in non-HIV specialties advocated by the Chief Medical Officer (24).

32. Section 1(1)(f) of the Human Tissue Act 2004 allows “relevant material” (which is defined as anything containing cells and would therefore include tissue, whole blood and other body fluids) to be used to obtain scientific or medical information about a person which may affect another person “if done with appropriate consent”. This means that where a source patient lacks capacity to consent (e.g. because they are unconscious), his/her tissue etc can only lawfully be tested for serious communicable diseases if it is reasonably held to be in his/her best interests in accordance with the Mental Capacity Act 2005. In the light of this, the General Medical Council withdrew its guidance that set out exceptional circumstances in which the testing of an existing sample might be justifiable (see Annex B). In the event of a deceased patient being the source of a needlestick injury and whose HIV status is unknown, the taking and testing of samples requires consent in accordance with the Human Tissue Act 2004. Assuming the deceased did not give consent (or refuse it) while alive, this can be obtained from a “nominated representative” (if appointed) or by a person in a “qualifying relationship” to the deceased.
33. As part of pre-test discussion, or before asking about a history of possible exposure to HIV, the source patient should first be informed about the incident and the reason for the enquiry, request for a test and to whom the results will be disclosed. The difficulties of the exposed health care worker’s situation should be discussed – either in terms of the worker not missing the opportunity to benefit from PEP, or conversely not being subjected unnecessarily to its potentially unpleasant short-term and unknown long-term side effects. Wherever possible, the health care worker’s identity should not be disclosed. It is understood

that consent to HIV testing is rarely withheld in these circumstances, when the approach is made in a sensitive manner.

34. Testing of source patients' blood should be conducted urgently. This is to minimise exposure to antiretroviral medication and to allay anxiety of the exposed individual. **It is recommended good practice that all hospitals have the capacity to obtain an HIV test result ideally within 8 hours and not more than 24 hours after source blood is taken.** Starting PEP, where appropriate, should not be delayed to await the result of source patient testing. The use of a rapid (near-patient) HIV test can reduce the time needed to rule out HIV infection to a few hours or less, and may be useful where obtaining a laboratory test result will be delayed. A negative result with a highly sensitive rapid test is reliable evidence that infection is not present. A positive test is presumptive evidence of HIV infection, but confirmatory tests should be performed.
35. Any source patient who is newly diagnosed HIV positive as a result of this process will need immediate access to specialist post-test counselling and assurances about confidentiality. Close support and clinical management will be needed on an ongoing basis. Source patients should also be informed promptly of HIV negative results, with any post-test discussion appropriate to individual circumstances (e.g. to address an ongoing risk identified through pre-test discussion and as a reminder about the window period if there has been recent personal risk). The possibility of a window period infection in the source patient should be addressed as part of the risk assessment, and PEP for the exposed worker may be recommended.

#### 2.4 Exposure to discarded needle/unknown source

36. Where it is not possible to identify the source patient (e.g. needlestick injury caused by a discarded needle), a risk

assessment should be conducted to determine whether the exposure was significant. This will be informed by considering the circumstances of the exposure and the epidemiological likelihood of HIV in the source. The use of PEP is unlikely to be justified in the majority of such exposures (25).

## Chapter 3: PEP

### 3.1 When to prescribe PEP

37. PEP should be recommended to health care workers if they have had a significant occupational exposure (see paragraph 26) to blood or another high-risk body fluid (see Annex A) from a patient or other source either known to be HIV infected, or considered to be at high risk of HIV infection, but where the result of an HIV test has not or cannot be obtained, for whatever reason.
38. PEP should not be offered after exposure through any route with low-risk materials (e.g. urine, vomit, saliva, faeces) unless they are visibly bloodstained (e.g. saliva in association with dentistry). Also, PEP should not be offered where testing has shown that the source is HIV negative, or if risk assessment has concluded that HIV infection of the source is highly unlikely. Exceptionally, PEP may be indicated following a negative test if there is reason to suspect the source may be seroconverting (i.e. in the window period).
39. When offering PEP it is important to take into account any views of the exposed health care worker. Depending on the outcome of the preliminary risk assessment, if the exposure was significant, the exposed health care worker may wish to consider starting PEP until further information is available about the source patient. In this way the option of possible benefit from prompt PEP will have been kept open. Changes can be made to the PEP regimen, including cessation, if further information becomes available.
40. If the HIV status of the source cannot be established, the exposed health care worker should have the opportunity to consider whether or not to continue PEP. Their decision should be informed by all that is known about the source patient in terms of past exposure to risk of HIV infection and also the nature and severity of the exposure. These

aspects should be considered together with the potential for unpleasant short-term adverse effects and unknown long-term effects of taking PEP drugs.

41. The relative risk of transmission may be increased considerably if the source patient has a high plasma viral load (e.g. at the time of seroconversion or in the later stages of HIV disease). It must be appreciated that the absolute risk is difficult to determine from plasma viral load alone due, for example, to differences in viral load between body compartments (e.g. plasma and genital tract, which is relevant to sexual transmission). Nevertheless, infectivity of all body fluids is likely to be reduced where plasma viral load is undetectable (26; 27).
42. The use of PEP drugs in special circumstances (e.g. pregnancy), the place of alternative drug regimens and viral drug resistance are discussed in Annex E. Drug interactions are considered in Annex F.

### **3.2 What to prescribe for PEP**

43. Annex C describes the currently recommended PEP starter regimen and the rationale for its choice. PEP is not a licensed indication for any of the antiretroviral drugs, which are therefore prescribed on an 'off-label' basis in the context of PEP. It is important that the ready accessibility of PEP starter packs does not conflict with appropriate prescribing practice.

### **3.3 Management of health care workers occupationally exposed to HIV: further issues, including follow-up**

44. Occupational exposure to known or suspected HIV-infected materials is always stressful and, for some, extremely so (28).
45. PEP is most likely to be effective when initiated as soon as possible (within hours, and certainly within 48–72 hours of exposure), and continued for at least 28 days. It should be noted that the evidence base on which these conclusions are based is limited (see Annex H for a summary of the



evidence). Therefore, PEP should be commenced as soon as possible after exposure, allowing for careful risk assessment, ideally within an hour. PEP is generally not recommended beyond 72 hours post-exposure. Decisions on initiation of PEP more than 72 hours after the exposure should be left to the discretion of local clinicians in discussion with the exposure recipient, in full knowledge of the lack of evidence of efficacy after this time point.

46. Following exposures for which PEP is considered appropriate, health care workers should be given time to discuss the balance of risks in their particular situation and they should be offered appropriate psychological support. They should be informed that knowledge about the efficacy and toxicity of drugs used for PEP is limited. It is important that their views about PEP are taken into account and that their preferences about what to discuss and with whom are respected. In particular, there may be someone in whom they have trust and to whom they would like to be referred.
47. The evaluation of the health care worker should cover medical history, including sexual history. Details of any existing medication should be established, as antiretroviral medications may have potentially serious interactions with other prescription or non-prescription drugs (see Annex F). Females should be asked specifically about the possibility of pregnancy (see Annex E). All exposed health care workers should be encouraged to provide a baseline blood sample for storage and a follow-up sample for testing (see Box 1, pages 21–23). The practice of taking a 6-month sample for storage only is inappropriate. It is sufficient to retain baseline samples for 2 years. The health care worker should be informed of the retention policy at the time the sample is taken.
48. All information about the health care worker and the source patient should be kept confidential. The designated doctor, who co-ordinates arrangements for source patient testing

and follow-up of the health care worker, is responsible for ensuring that issues relating to confidentiality are addressed.

49. PEP should normally be continued for 4 weeks. Every effort should be made to facilitate adherence to a full 4-week regimen. This time course, or the drugs used, may need to be modified if problems of tolerance and/or toxicity are encountered (see also Annex C). Since nausea is a common problem, the prescription of prophylactic anti-emetics should be considered. If severe nausea is experienced and is a deterrent to taking PEP, expert advice should be sought. Anti-motility drugs may be helpful if diarrhoea develops – a common side effect of protease inhibitor therapy.
50. Occupational health practitioners may choose to refer exposed health care workers to HIV, GUM or infectious disease departments for regular medical follow-up during the period of PEP, to monitor possible toxicity and adherence to the antiretroviral regimen. Close follow-up and encouragement, ideally on a weekly basis at least, from a clinician experienced in prescribing antiretroviral therapy is likely to help improve adherence and deal promptly with concerns and complications. Any need for sickness absence associated with adverse effects of PEP drugs following an occupational exposure should preferably not contribute to an individual's sickness absence record (for monitoring and absence control purposes).
51. All health care workers occupationally exposed to HIV should have follow-up counselling, post-exposure testing and medical evaluation **whether or not** they have received PEP. In addition, they should be encouraged to seek medical advice about any acute illness that occurs during the follow-up period. Illnesses characterised by fever, rash, myalgia, fatigue, malaise or lymphadenopathy may represent a seroconversion illness. Some of these symptoms may, however, be side effects of antiretroviral medication (see also Annex C).

52. It is recommended that, where health care worker follow-up is conducted outside the Occupational Health department, for example by the GUM or Infectious Diseases (ID) department, the health care worker also arranges a meeting/updates occupational health or gives consent for GUM/ID to provide the follow-up information to occupational health. This will ensure that records are complete for local review of PEP practice (see paragraph 79) and for reporting to surveillance systems (Annex D), e.g. what drugs were prescribed, tolerability of the regimen, side effects, premature discontinuation and results of any post-exposure testing.

### **Box 1: Recommended schedule of serological investigations following occupational exposure to HIV**

Until now, EAGA has recommended that follow-up testing of health care workers be performed at 12 and 24 weeks post-exposure (or 24 weeks after cessation of PEP if prescribed), using the most sensitive tests (i.e. fourth generation combined antibody/antigen assays). A baseline sample should be taken for storage. Serological testing at 6 weeks is not routinely warranted as a negative serology result at this stage is inconclusive.

Implementation of this follow-up schedule has been monitored through the national surveillance of occupational exposure to blood-borne viruses in health care workers operated by the Health Protection Agency (see Annex D) (17). Of 276 health care workers exposed to an HIV-positive source in 2005–06, fewer than half (46% (126/276)) are known to have completed 24-week follow-up (17).

There has been only a single case of HIV seroconversion in the UK where the health care worker took PEP (18) and no cases of delayed seroconversion (i.e. beyond 12 weeks from exposure) have been reported from international collaborators since the widespread use of PEP (29).

Data on the optimal duration of follow-up are limited. However, based on expert opinion, EAGA now recommends, **as a minimum, that follow-up should be for at least 12 weeks after the HIV exposure event or, if PEP was taken, for at least 12 weeks from when PEP was stopped.**

There are a number of practical arguments in favour of terminating follow-up with serological testing a minimum of 12 weeks after the exposure incident/cessation of PEP. The principal reasons are:

- a negative test at 12 weeks provides a very high level of confidence of freedom from infection (due to high sensitivity of combined antibody/antigen serological assays);
- to minimise the period of anxiety suffered by exposed health care workers waiting for the 'all clear';
- to focus efforts and resources of Occupational Health departments on improving completeness of 12-week follow-up testing;
- in the majority of cases where seroconversion has occurred following occupational exposure despite the use of triple PEP, seroconversion has been detected within 12 weeks of exposure (29); and
- for consistency with the advice following a potential sexual exposure (presenting too late for consideration of PEP), where a negative test at 12 weeks post-exposure provides reassurance of freedom from infection.

Longer follow-up with additional testing may be indicated in complex cases, for example if the exposed worker is immunocompromised, experiences an illness compatible with an acute retroviral syndrome (regardless of the interval since exposure) or where the source patient is dually infected. In the case of HIV and hepatitis C co-infection, delayed seroconversion for HIV (documented at 7 months post sexual exposure) has been reported (30). Testing for the other blood-borne viruses should follow recommended schedules.

Plasma RNA polymerase chain reaction (PCR) testing has no role to play in routine follow-up of occupational exposures to HIV. Since these tests are optimised to measure very low levels of HIV RNA, they have a relatively high rate of false-positive results and a low positive predictive value when used to detect occupational transmission.

53. Pending follow-up, and in the absence of seroconversion, health care workers who have been exposed to HIV occupationally need not be subject to any modification of their working practices, for example avoidance of exposure-prone procedures.<sup>2</sup> Advice should, however, be given to reinforce the importance of infection control measures, safer sex and avoiding blood donation during the follow-up period. This position reflects a judgement that the risk to the health care worker of becoming infected may both be high enough to justify taking PEP and engaging in safer sex but remote enough not to warrant modification of work

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2 Exposure-prone procedures are those where there is a risk that injury to the health care worker may result in exposure of the patient's open tissues to the blood of the health care worker. These procedures include those where the worker's gloved hands may be in contact with sharp instruments, needle tips or sharp tissues (spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space, where the hands or fingertips may not be completely visible at all times. An illustrative list of exposure-prone procedures can be found in reference 31.

activities (because the risk to the patient is the product of the low risk of the health care worker becoming infected multiplied by the low risk of onward transmission to the patient through exposure-prone procedures).

54. If a health care worker presents having recently been exposed to HIV **non-occupationally**, a risk assessment should be conducted of the actual exposure. PEP may be indicated if the worker presents within 72 hours of the exposure event (3). The risk of seroconversion may be substantially higher from a non-occupational exposure. Where the exposure, or most recent in a series of exposures, is within the last 3 months, the worker may be in the window period for seroconversion. If he/she performs exposure-prone procedures, modifying their practice during the follow-up period needs to be considered.

### 3.4 HIV seroconversion

55. If, during the follow-up period, HIV infection is diagnosed, the health care worker should be advised and managed in line with EAGA recommendations (31). Health care workers who have acquired HIV infection because of exposure to HIV-infected material in the workplace, e.g. a significant occupational exposure such as a needlestick injury, may be eligible for benefits.
56. The NHS Injury Benefits Scheme (or HPSS Injury Benefits Scheme in Northern Ireland) is part of the terms and conditions of service for NHS employees. It provides temporary or permanent benefits for all NHS employees who are either on leave of absence (usually certified sick leave) and lose pay, or who have to leave their NHS job and suffer a permanent reduction in their earning ability of more than 10%, because of an injury or disease that is wholly or mainly attributable to the duties of their NHS employment.
57. The scheme is available also to general medical and dental practitioners working in the NHS. Under the terms of the

scheme it must be established whether, on the balance of probabilities, the injury or disease was acquired during the course of NHS work. Further useful information is available from: <http://www.injurybenefit.nhsbsa.nhs.uk/>

58. At least 12 weeks should elapse after cessation of PEP before a negative serology test is used to reassure the individual that infection has not occurred. Following any occupational exposure to HIV, whether or not PEP was prescribed, health care workers should attend for occupational health follow-up for such a period, and be prepared to report symptoms of concern at any time.

### 3.5 Making PEP available: immediate access

59. It is recommended that, for optimal efficacy, **PEP should be commenced as soon as possible after exposure, allowing for careful risk assessment, ideally within an hour. PEP is generally not recommended beyond 72 hours post-exposure.** There may be circumstances where it is appropriate that the exposed worker is offered the initial doses immediately, pending fuller discussion and risk assessment as soon as practicable.
60. Starter packs of the recommended drugs should be kept in a number of readily accessible and well advertised places, including:
  - Occupational Health department;
  - Pharmacy;
  - A&E department; and
  - specific wards or departments.
61. Each pack should contain a minimum 3-day course of the drugs, sufficient to cover weekends and bank holidays, with two packs to be given to cover longer bank holiday weekends.

62. Arrangements will need to be in place to ensure that starter packs are stored appropriately and that the drugs have not passed their expiry date.
63. Training and clear protocols should be given to personnel who might be responsible for initial administration of drugs.

### 3.6 Making PEP available: policies and protocols

64. Consultants in Communicable Disease Control or, in Scotland, Consultants in Public Health Medicine (CD & EH) should help ensure that the management of NHS bodies and other health care settings (including private facilities) is aware of its responsibility to make adequate arrangements for staff (8). This would include ensuring that A&E departments are aware of, and have accepted, their responsibility to provide cover, where applicable. As part of the commissioning process, these arrangements should be audited.
65. NHS bodies have a duty to adhere to policies and protocols applicable to infection prevention and control, including the prevention of occupational exposure to blood-borne viruses (8). Where appropriate, standard PEP starter packs should be available on site for use following occupational exposure. In those settings where PEP is not available on site, the policy and protocol should include information about where the starter pack of drugs may be obtained.
66. Managers should ensure that PEP policies and protocols reflect current best practice.
67. To minimise delay in seeking advice about PEP, it is important that all health care workers are aware of the possible risks from occupational exposure and the need to seek urgent advice following any percutaneous or other potentially significant exposure. All should be aware of how to report an exposure, and to whom. Occupational Health departments should issue regular reminders to all those for whom it is responsible, including non-hospital health



care workers who have contracted cover for post-exposure management (e.g. general medical and dental practitioners and their staff).

68. Local factors will vary between trusts and other health care settings and first-line provision of PEP will depend on these.
69. Sources of expert advice should be indicated in local policies and may include:
  - Consultants working in HIV medicine, Virology, Microbiology, Infectious Diseases, GUM, Occupational Health; and
  - Public Health Physicians (particularly those with responsibility for infection control such as Consultants in Communicable Disease Control or, in Scotland, Consultants in Public Health Medicine (CD & EH)).
70. In trusts where there is a consultant occupational physician in post, it is likely that arrangements will be co-ordinated through the Occupational Health department. Where there is no consultant occupational physician, hospitals may group together on a geographical basis for advice through a central consultant occupational physician.
71. Where there is no consultant occupational physician, the policy should specify who is responsible for provision of PEP and its follow-up according to local expertise and logistics.
72. In view of the need for very prompt treatment and the serious consequences of HIV seroconversion, significant occupational exposure to known or possible sources of HIV constitutes a medical emergency. Outside normal working hours, A&E departments would usually be expected to assume responsibility for assessment of occupational exposure and providing PEP. As the first point of contact for any such exposure, whether or not this arose in the hospital, there is a need to give appropriate priority to potential PEP candidates. A&E staff, such as junior medical staff and triage nurses, will require specific training regarding assessment

of the need to access immediate expert advice and about supplying an initial dose of PEP, and clear protocols to follow. As key 'stakeholders', it is important that A&E departmental staff are involved in developing and agreeing local PEP policies and protocols.

73. In other health care settings, it will be important for general medical and dental practitioners, their staff and other community health workers to ensure they have arrangements in place for rapid access to urgent advice, and PEP where indicated. This will be particularly important for GPs and networks of carers who know they are looking after one or more HIV-infected patients – for instance, in the context of terminal illness. If friends or relatives are providing clinical care to HIV-infected patients in the community which involves a risk of exposure to HIV-infected material, they should be advised about infection control measures to prevent exposure (21; 32), and the importance of reporting any exposure incidents to the A&E department without delay.
74. Those responsible for occupational health and safety of certain non-health care workers (such as police, fire and prison service personnel), who may also be at risk of occupational exposure to HIV, should ensure that there are similar arrangements in place for access to advice in such an emergency and assessment and treatment where appropriate.
75. Back-up information for community health care workers via a widely publicised local helpline may be helpful, as well as locally disseminated guidelines on appropriate local sources of expert advice as in paragraph 69 above.
76. It would normally be appropriate for the starter packs of PEP drugs to be made available to community-based health workers through A&E departments on a 24-hour basis.

77. It is suggested that local PEP policies should include the following information:

- occupational risks of HIV for health care workers;
- definition of “significant occupational exposure” (see paragraphs 26 and 27);
- clear protocols for post-exposure assessment, management and prescription of PEP drugs;
- rationale for therapy offered;
- sources of emergency advice and sources of subsequent support for the psychological consequences of the incident;
- out-of-hours access (e.g. when the Occupational Health department is closed);
- procedures following an occupational exposure;
- timing and duration of PEP;
- sites of starter packs;
- possible side effects of drugs and possible interactions with other medication (including ‘over the counter’ preparations);
- ensuring that local sources of expertise have access to appropriate training to maintain up-to-date knowledge of issues surrounding PEP, and to sources of expert advice for consultation where indicated, such as physicians experienced in the treatment of HIV and familiar with considerations for the use of PEP;
- arrangements for follow-up visits, follow-up testing, record keeping and confidentiality;
- voluntary reporting of occupational exposures to the Health Protection Agency’s Centre for Infections or Health Protection Scotland (see Annex D, paragraphs 1 and 2). Specific types of accident, and development of HIV disease as a consequence of occupational exposure,

require reporting under the Reporting of Injuries, Diseases and Dangerous Occurrences (RIDDOR) legislation (see Annex D, paragraphs 4–6); and

- local procedures for reporting accidents and keeping lists of laboratory employees intentionally working with Hazard Group 3 pathogens (COSHH schedule 3).

78. **Staff training** issues include:

- avoidance of occupational exposure to HIV by adherence to safer working practices and use of personal protective equipment as appropriate (8);
- action to be taken following possible exposure including immediate first aid. Clear information should be provided to all health care workers about where emergency advice and assessment can be obtained;
- the importance of reporting all percutaneous and other potentially significant occupational exposures according to local arrangements;
- encouraging health care workers particularly at risk to maintain awareness of the principles of PEP. Some may wish to consider the pros and cons of PEP before any event, although views may change depending on the particular circumstances of an exposure; and
- training of junior staff (e.g. triage nurses and junior doctors in A&E departments) who may be called upon to assist a colleague immediately after an incident and who may be responsible for supplying a starter pack. Detailed and clear protocols should be available.

79. The Occupational Health department (or other designated department for reporting blood exposures) should keep a database of exposure incidents. It is very important that all exposure incidents are reviewed, whether or not PEP was prescribed:

- to consider how recurrence might be prevented; and
  - to inform staff training as appropriate.
80. Responsibility for review should be made clear. It may vary according to local arrangements for provision of occupational health services and management of exposure incidents. Hospital or Community Infection Control Teams should be involved.

## Chapter 4: UK health care workers seconded overseas including students on electives

81. Antiretroviral medication has become more widely available in high HIV prevalence countries. Prior to departure, enquiries should be made as to whether PEP protocols are established in the centres where UK health care workers will be based. Only if PEP is not available, or it has not been possible to establish in advance whether it is available, should they consider taking a PEP starter pack with them (see paragraph 90).
82. There are occasions when health care workers may leave the UK to work abroad, some of whom intend to return to work in the UK in the future. Included in such a group are those UK medical, dental and nursing students who travel abroad during an 'elective' period to gain experience, often in developing countries. On their return to work in the UK, these health care workers may be subject to additional health checks (as defined in reference 33) if they may have been exposed to serious communicable diseases while away.
83. In the UK, as well as elsewhere, it is important that all who may perform procedures which involve a risk of significant occupational exposure are well versed in the principles of blood-borne virus infection control precautions (21; 34). These principles should be introduced in medical, dental school and nursing training curricula prior to the start of clinical attachments (34) and, as a minimum, prior to the performance of any invasive procedures such as venepuncture. At the same time, all students should be made aware of the importance of reporting any occupational exposure, so that consideration can be given to the need for PEP. These messages should be reinforced at regular intervals.

84. The risk of nosocomial HIV transmission for health care workers working overseas in low-income countries may be increased by a combination of factors (34–37). Firstly, the relatively much higher prevalence of HIV infection in the patients being cared for than in the UK. Secondly, lack of resources to implement standard infection control measures adequately and poor or inadequate equipment and facilities leading to increased risk of exposure. Thirdly, in the case of students seeking work experience, their relative inexperience/lack of technical skills may increase their likelihood of exposure to blood and other body fluids.
85. Health care workers (including students) intending to work in health care settings overseas should be advised about health and safety issues when working outside the UK, including the risk of occupational and other exposure to HIV.
86. Medical, dental and nursing schools should consider developing accessible, regularly updated advice for students considering electives overseas about measures to keep the risk to their health to a minimum, including information about PEP (36–38). Specific consideration should be given to the risk of occupational exposure to HIV and how to minimise this.
87. Advice should include up-to-date information about the prevalence of HIV infection in the country that a student is considering for an elective. Students considering electives in high HIV prevalence situations should be made aware of the occupational consequences in terms of ability to pursue a career involving exposure-prone procedures (31; 33). Some medical schools may advise students against involvement in clinical procedures that carry the highest risk of occupational exposure – for instance in surgery or obstetrics – in areas of high HIV prevalence.
88. Pre-travel briefing might include reinforcement of advice on immediate post-exposure first aid measures (see paragraph

23), and training on self-assessment of occupational exposure (i.e. whether an exposure is or is not significant with the potential to transmit HIV) as considered earlier in this document (paragraph 26). Advice should also be given about how to make some assessment of the likelihood of HIV infection in the source, as many people who are infected with HIV in less developed countries will not have had their infection diagnosed.

89. Procedures should be clarified for access to urgent advice in the event of any significant occupational exposure to a source considered likely to have HIV infection. Even if not working in a major centre, it may be possible for arrangements to be in place for advice to be obtained as soon as practicable at the nearest major centre, or alternatively by telephone from the UK source of expert advice to their own employer/medical school.
90. Employers and medical, dental and nursing schools should consider making 7-day starter packs of PEP drugs available to workers/students travelling to countries where antiretroviral therapy is not commonly available. These packs should include the same triple PEP regimen as recommended for use in the UK. The more widespread use of antiretrovirals in resource-poor settings has increased the likelihood of occupational exposure to resistant virus, making a triple PEP regimen necessary. Any student/other worker issued with a starter pack including a protease inhibitor should be warned about increased toxicity in the event of dehydration.
91. The principles about starting PEP as soon as possible after a significant occupational exposure, and the known short-term and unknown long-term adverse effects, should be made clear to those issued with PEP drugs.
92. In circumstances where it has been considered necessary to start PEP, expert advice by phone will also be needed to help the student/other worker decide whether the regimen needs



to be continued for four weeks and, if so, about the need for urgent repatriation. This may be appropriate if further treatment and follow-up cannot reasonably be accessed in the foreign country. The possibility of insuring against the need for repatriation in the event of a medical emergency requiring treatment should be explored with the travel insurance provider, prior to leaving the UK.

93. It is important that the possibility of occupationally acquired HIV infection is specifically considered after occupational exposure in countries of high HIV prevalence, and excluded before performing exposure-prone procedures in the UK (33). On return from working abroad in countries where they may have been exposed to serious communicable diseases, all health care workers, including students, should undergo an occupational health risk assessment, as recommended in reference 33. After discussion of the risk(s) to which they may have been exposed, HIV testing may be considered appropriate (in reference 31 – paragraphs 4.8–4.9). Of the 14 'possible' occupationally acquired HIV infections reported in the UK, 13 health care workers had worked in areas of high HIV prevalence (specifically, Africa and the Indian Sub-continent) and were probably infected abroad (29).
94. The outcomes of such risk assessments will help medical, dental and nursing schools steer future students away from placements for electives where the risks to which they may be exposed – e.g. by poor facilities for protecting themselves against blood-borne viruses – outweigh the possible benefits otherwise perceived.

## Chapter 5: Exposure outside the hospital setting

95. For the purposes of this document, 'outside the hospital setting' refers to exposures in the wider community, such as might occur through sharing of drug injecting equipment with someone with HIV or injury resulting from contact with a discarded needle. Sexual exposure to HIV is specifically excluded from this document because separate detailed guidance is available from the British Association for Sexual Health and HIV (BASHH) (3). (See: <http://www.bashh.org/documents/58/58.pdf>) EAGA endorses the BASHH guidance as an authoritative interpretation of the available evidence.

### 5.1 Equity of access and management

96. Primary care trusts (PCTs) are responsible for commissioning occupational health services for their own staff and for GPs and dentists and their staff in the PCT area. This is usually achieved by means of a contract with a local NHS occupational health service. Services for the general public are typically provided by A&E departments or GUM clinics. These are the arrangements for England. Similar ones, reflecting local health service structures, are in place in the other countries of the UK. Provision of monitoring and follow-up for health care workers taking PEP will therefore vary according to local arrangements.
97. All inoculation injuries with the potential to transmit HIV, whether they occur in the community, in a health care environment, to a health care worker or another individual, should be managed in the same way. An individual risk assessment of the circumstances of the exposure should be conducted and this, along with the other considerations detailed in this guidance, must form the basis for deciding whether PEP is started.

98. Owing to the complexity of the risk assessment process and the desirability of having PEP prescribed by a physician experienced in the use and monitoring of antiretroviral medications (for side effects, drug interactions etc), occupational health services (backed up by other services as required) have been identified as the main providers of occupational PEP.
99. However, where a GP is responsible for providing occupational health cover for a practice or group of practices he/she may prescribe at least a starter pack of PEP, before referring the exposed person to an HIV physician for monitoring and follow-up.
100. Inoculation injuries with the potential to transmit HIV may also place the individual at risk of other blood-borne virus infections (e.g. hepatitis B and C). Testing and follow-up for other infections as appropriate should be undertaken, and the need for post-exposure prophylaxis for hepatitis B should be considered.

## 5.2 Other occupational groups

101. Those responsible for occupational health provision to other professional groups who may be at some risk of exposure to HIV-infected material outside health care settings (e.g. police, fire service, prison service, voluntary aid agencies and the armed forces) may wish to use these guidelines as a basis for developing guidance appropriate to the particular occupational setting.
102. A working group has issued advice to the Scottish Executive on protecting front-line workers (police, prison and fire and rescue service staff) and victims of crime from blood-borne viral infections and from anxiety about them (5).

## 5.3 Children

103. If a child has been exposed, specialist advice from a paediatrician experienced in the field of HIV should be

sought. PEP guidelines for children exposed to blood-borne viruses can be found on the website of the Children's HIV Association of UK and Ireland (<http://www.chiva.org.uk/protocols/pep.html>).

#### 5.4 Factors affecting use and efficacy of non-occupational PEP

104. Factors affecting the use of non-occupational PEP include the probability of HIV infection in the source (e.g. the injecting equipment sharer or discarded needle), the likelihood of transmission by the particular exposure and the interval between the exposure and presentation for PEP. The efficacy of non-occupational PEP depends on the drugs used (especially if exposure was to resistant virus), the exposed person's adherence to the PEP regimen and whether the incident was isolated or recurrent (3).
105. From the point of a decision being reached that it is appropriate to prescribe PEP after non-occupational exposure, all the same considerations apply as for occupational exposure. In addition, there may be a need for counselling to prevent recurrence (e.g. where exposure occurred through sharing of drug injecting equipment).

## **Annex A: Body fluids and materials which may pose a risk of HIV transmission if significant occupational exposure occurs**

Amniotic fluid

Blood

Cerebrospinal fluid

Exudative or other tissue fluid from burns or skin lesions

Human breast milk

Pericardial fluid

Peritoneal fluid

Pleural fluid

Saliva in association with dentistry (likely to be contaminated with blood, even when not obviously so)

Semen

Synovial fluid

Unfixed human tissues and organs

Vaginal secretions

Any other body fluid if visibly bloodstained

## Annex B: General Medical Council (GMC) guidance

The guidance in this annex is provided by the GMC.

### **Good Medical Practice (2006) (39)**

79. *If you know that you have, or think that you might have, a serious condition that you could pass on to patients, or if your judgement or performance could be affected by a condition or its treatment, you must consult a suitably qualified colleague. You must ask for and follow their advice about investigations, treatment and changes to your practice that they consider necessary. You must not rely on your own assessment of the risk you pose to patients.*

### **Serious Communicable Diseases (1997) – extract from GMC website<sup>3</sup>**

The GMC guidance on *Serious Communicable Diseases* (1997) was withdrawn on 13 November 2006. In response to a number of recent inquiries, this is a reminder that the issues covered in the 1997 guidance are dealt with in other GMC guidance or are now governed by legislation.

Current GMC advice on consent to testing can be found in *Seeking Patients' Consent: the ethical considerations* (recently replaced by *Consent: patients and doctors making decisions together*). Our advice on disclosure of confidential patient information to third parties (such as a person's infection status) can be found in *Confidentiality: protecting and providing information*.

Decisions about testing the infection status of incapacitated patients, after a needle-stick or other injury to a healthcare worker, must take account of the current legal framework governing capacity issues and the use of human tissue. In

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3 See: [http://www.gmc-uk.org/guidance/serious\\_communicable\\_diseases/index.asp](http://www.gmc-uk.org/guidance/serious_communicable_diseases/index.asp)

England, Wales and Northern Ireland this area is covered by the Human Tissue Act 2004 and the Mental Capacity Act 2005 (E&W only). In Scotland this area is covered by the Adults with Incapacity (Scotland) Act 2000 and the Human Tissue (Scotland) Act 2006. As we understand it, current law does not permit testing the infection status of an incapacitated patient solely for the benefit of a healthcare worker involved in the patient's care. Concerns about how best to care for healthcare workers who may have had high risk exposure to a serious communicable disease, where the patient's infection status is not known, should be raised with local occupational health advisers, and legal advice should be sought where necessary.

### **Further information**

Legislation: Office of Public Sector Information

Human Tissue Regulations: Department of Health

Human Tissue Codes of Practice: Human Tissue Authority

Mental Capacity Codes of Practice: Ministry of Justice

Adults with Incapacity (Scotland) Act 2000 – Legislation and Codes of Practice: Scottish Executive

## Annex C: What to prescribe for PEP

1. Antiretroviral agents from three classes of drug are currently licensed for first-line treatment of HIV infection, namely:
  - nucleoside/nucleotide analogue reverse transcriptase inhibitors (NRTIs);
  - non-nucleoside reverse transcriptase inhibitors (NNRTIs); and
  - protease inhibitors (PIs).
2. Zidovudine (an NRTI) is the only drug to date which has been studied and for which there is evidence of a reduction in risk of HIV transmission following occupational exposure (9).<sup>4</sup> However, as no antiretroviral drug has been licensed for PEP, they can only be prescribed for PEP on an 'off-label' basis.
3. In HIV-infected patients, triple therapy has proved more effective than mono- or dual-therapy in suppressing HIV replication and avoiding the emergence of viral resistance. The US guidelines recommend two-drug PEP regimens following lower-risk incidents and three-drug regimens only for higher risks (14). This two-tier approach adds to the complexity of the risk assessment process, at the expense of greater potency and protection for the exposed worker, and is not recommended by EAGA. The main arguments in favour of two-drug PEP (fewer side effects, better adherence and course completion rates) (40) are being addressed through switching to better-tolerated agents with lower pill burdens. At the same time, a potent three-drug PEP regimen is preferred because resistance to antiretroviral drugs is found at significant levels in both treated and untreated infected individuals in the UK (10; 11).

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4 Zidovudine is no longer recommended for PEP starter packs, preference being given to newer drugs with better tolerability.



4. Information about the virus present in the source patient and, if known, any sexual partner of the source patient will be relevant when choosing appropriate PEP drugs. Similarly, information about the source patient's (and his or her sexual partner's) previous and current antiretroviral therapy may also be important. Any information available in the source patient's medical record about antiretroviral drug resistance should be used to inform the choice of PEP drugs (see Annex E).

### Starter regimen

5. After due consideration of storage/stability issues, side-effect profiles (41–43), drug interactions, drug resistance and regimen simplicity (i.e. reduced pill burden and food restrictions), the following regimen is now recommended for PEP starter packs:<sup>5</sup>

One Truvada tablet (300mg tenofovir and 200mg emtricitabine (FTC)) once a day

*plus*

Two Kaletra film-coated tablets (200mg lopinavir and 50mg ritonavir) twice a day

6. There are no food restrictions associated with this regimen and the PEP pack can be stored at room temperature.
7. This new regimen is also consistent with the generic regimen of two NRTIs plus boosted PI recommended for PEP following non-occupational exposure (3). All primary care trusts in England have been directed to make PEP available for their local populations as part of sexual health services (4). Harmonisation of the regimens for occupational and non-occupational PEP has the potential to simplify access arrangements.

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5 Truvada plus Kaletra is the preferred regimen, but Combivir plus Kaletra may be considered as an option if there are difficulties sourcing starter packs containing Truvada. Due to concerns about long-term stability outside the original container, some Prepacking Units may be unable to supply starter packs containing Truvada.

8. While the above regimen is recommended for emergency starter packs, other NRTI and PI combinations could be used where the physician considers them more appropriate for individual patients. Other new classes of drugs, such as entry inhibitors and integrase inhibitors, may have a role in cases of resistant source virus, but there is currently no evidence for their use in this situation.

### Side effects

9. All of the antiretroviral agents have been associated with side effects. Many of these can be managed symptomatically. Side effects of the NRTIs (e.g. tenofovir and emtricitabine) include gastrointestinal (e.g. nausea, diarrhoea) as well as dizziness and headache. In clinical trials of Kaletra, the most commonly reported side effect was diarrhoea, followed by other gastrointestinal disturbances, asthenia, headache and skin rash (44).
10. Those providing advice on and protocols for prescribing PEP should maintain awareness of advances in HIV therapeutics, potential side effects, adverse drug reactions and drug interactions, and seek further expert advice where necessary. Prescribers need to be aware of the greater potential for drug interactions between Kaletra (due to the ritonavir component of the formulation) and other prescription and non-prescription medicines (relative to the PIs previously recommended for PEP) and counsel patients accordingly. For sources of further advice about drug interactions, see Annex F.
11. Inclusion of an NNRTI in PEP regimens (occupational or non-occupational) is not recommended. Both of the NNRTIs licensed for treatment of HIV infection in the UK (nevirapine and efavirenz) are associated with short-term toxicity: nevirapine has the potential to cause severe rashes (which may be confused with rash associated with HIV seroconversion) and sometimes Stevens–Johnson syndrome;

efavirenz is associated with neurological side effects and is also contraindicated in pregnancy, but it has a lower incidence and severity of rash than nevirapine. Serious adverse events (including life-threatening hepatotoxicity) have been reported in health care workers taking nevirapine as part of PEP (45; 46). There is evidence of incremental improvement in tolerability of PEP regimens as the protease inhibitor component has evolved (i.e. Kaletra replacing nelfinavir which replaced indinavir) with a stable zidovudine/lamivudine backbone (47).

12. If symptoms believed to arise from PEP are distressing and cannot be managed symptomatically and the health care worker feels unable to continue to adhere to the regimen, expert advice should be sought about suitable substitutions. This process should be informed, as before, by considerations of the source patient's antiretroviral history if known.
13. Adverse reactions associated with antiretroviral drugs should be reported using Yellow Cards (available in the back of the British National Formulary) to:

Medicines and Healthcare products Regulatory Agency  
CHM Freepost  
London  
SW8 5BR

Telephone: 0800 731 6789 or 020 7084 2000

Alternatively, Yellow Cards can be completed via the website: <http://www.yellowcard.gov.uk>

14. Any drug regimen should take into account the following factors:
  - whether the health care worker is or may be pregnant (see Annex E);
  - whether the health care worker has an existing medical condition;

- the potential for interaction with other medications (see Annex F); and
- the possibility that the virus may be resistant to one or more of the drugs, or where the exposed health care worker has been handling resistant virus in a laboratory (see Annex E).

**In all these circumstances expert advice should be sought.**

15. There may be local variations in the choice of regimen used. As newer antiretroviral drugs are developed, it is likely that other drugs will become the preferred regimen for PEP. Managers should ensure that PEP policies and protocols reflect current best practice.

# Annex D: Reporting of occupational exposures to HIV

## Reporting to HPA Centre for Infections (Cfi) or, in Scotland, to Health Protection Scotland (HPS)

1. Occupational health physicians and clinicians involved in the care of health care workers are encouraged to report occupational exposure to HIV (in complete confidence) to Cfi or HPS. By doing this, central data can be analysed so that:
  - the size of the problem and the degree of risk can be quantified;
  - working practices and procedures which are particularly risky may be identified; and
  - the side effects and benefits of prophylaxis may be assessed.
2. To report an occupational exposure in England, Wales or Northern Ireland to the surveillance scheme, please contact the Occupational Exposure Surveillance Team, HIV/STI Department, HPA Centre for Infections, 61 Colindale Avenue, London NW9 5EQ (Tel. 020 8327 7095). It is anticipated that a reporting system in Scotland will be implemented in 2008. Health care professionals should contact the HIV/STI Team, HPS, Clifton House, Clifton Place, Glasgow G3 7LN (Tel. 0141 300 1100) for further details.
3. Background to the surveillance scheme and summaries of the data collected can be found at: [http://www.hpa.org.uk/infections/topics\\_az/bbv/occ\\_exp.htm](http://www.hpa.org.uk/infections/topics_az/bbv/occ_exp.htm)

## Reporting of occupational exposure to HIV to the Health and Safety Executive (HSE)

4. In the event of exposure to HIV, employers may be required to report the event to HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences (RIDDOR) Regulations 1995. The most likely requirement, if any, may be the need to report a **dangerous occurrence**; namely *"Any accident or incident which resulted or could have resulted in the release or escape of a biological agent likely to cause severe human infection or illness."*
5. Cases of HIV infection resulting from exposure in the health care setting will also normally be reportable as **diseases** within the meaning of RIDDOR, i.e. resulting from *"work with micro-organisms; work with live or dead human beings in the course of providing any treatment or service in conducting any investigation involving exposure to blood or body fluids; work with animals or any potentially infected material derived from any of the above."*
6. HSE have an InfoLine (0845 345 0055) for general queries relating to RIDDOR or COSHH. Reports under RIDDOR can be made by contacting the Incident Contact Centre on 0845 300 9923 (Monday to Friday 8.30am to 5.00pm) or electronically via the HSE website <http://www.hse.gov.uk/riddor/index.htm>

## Serious Untoward Incident reporting system

7. In England, reporting of Serious Untoward Incidents associated with infection should be via the normal reporting system for all Serious Untoward Incidents, from the trust to the strategic health authority for onward reporting as appropriate. Further details can be found in Department of Health guidance (48). Similar arrangements, reflecting local health service structures, are in place in the other countries of the UK.

# Annex E: PEP: special circumstances

## Viral drug resistance

### Source patient

1. For known positive sources, information about drug resistance should be used to guide decisions about PEP. Resistance should be suspected if there has been prolonged treatment with any antiretroviral, where there is clinical progression of disease or a persistently increasing viral load and/or a decline in CD4 lymphocyte count despite therapy, or a lack of virological response to a change in therapy.
2. The HIV-infected source patient will fall into one of these categories:
  - hitherto undiagnosed; in this case, prevalence of resistance to any class of drug can be estimated as 5–10% (11);
  - already diagnosed, and untreated; these patients are increasingly likely to have had a resistance test undertaken, since baseline testing is recommended (49);
  - on treatment with undetectable viral load; they will be of very low infectivity, and will also probably have had a baseline resistance test;
  - on treatment with detectable viral load; they are likely to have resistant virus and also a recent resistance test.
3. Resistance is not all or none, and the drugs recommended for the PEP starter pack – tenofovir/emtricitabine and lopinavir/ritonavir – will retain useful activity against the most common resistant viruses in the UK. Therefore, concerns over resistance should not delay standard PEP, which should be initiated as soon as possible after the incident.

4. In US and Brazilian studies, a high prevalence of drug-resistant HIV has been found among source patients for occupational HIV exposures (50; 51). It is therefore important to take account of the results of a previous resistance test. If this suggests the standard PEP regimen would be poorly effective, treatment should be altered, taking account of the views of an expert in antiretroviral therapy/drug resistance.

### **Laboratory staff**

5. In the case of exposure of laboratory-based staff who work with drug-resistant virus, either because of routine resistance testing or research work on live viruses, there must be provision within local PEP protocols to obtain an immediate expert opinion on appropriate treatment.

### **Pregnancy**

6. Pregnancy does not preclude the use of HIV PEP. Expert advice should always be sought if PEP is considered indicated for a female health care worker who is pregnant, after assessment of the circumstances of the exposure and of the source patient. Urgent pregnancy testing should be arranged for any female worker who cannot rule out the possibility of pregnancy, as part of the evaluation prior to the exposed worker reaching a personal, informed decision about starting PEP.
7. The British HIV Association has published guidelines for prescribing antiretroviral therapy in pregnancy (52). There has been no indication of particular problems for the babies of HIV-infected women who have become pregnant while already on antiretroviral medication. It should be noted that there is limited experience of the use in pregnancy of some of the newer drugs.



8. A pregnant health care worker who has experienced an occupational HIV exposure should be counselled about the risks of HIV infection, about the risks for transmission to her baby, and about what is known and not known about the potential benefits and risks of antiretroviral therapy for her and her baby, to help her reach an informed personal decision about the use of PEP.
9. Decisions on the use of specific drugs in pregnancy may be influenced by their individual adverse effects. For example, drugs that may cause nausea may exacerbate pregnancy-associated nausea. Efavirenz is contraindicated in pregnancy and not recommended for inclusion in PEP regimens (see Annex C).

## Annex F: Interactions of antiretroviral medications with commonly used medicinal products

1. Antiretroviral medications may have potentially serious interactions with other prescription or non-prescription drugs. These can affect patient safety and the effectiveness of prophylaxis. Information on interactions changes rapidly with advances in therapeutics, so it is important to use up-to-date sources. **It is always advisable to check with a pharmacist.**

### Sources of information

- Summary of product characteristics for the specified medicinal products
- British National Formulary
- Interaction charts produced by the Liverpool HIV Pharmacology Group (<http://www.hiv-druginteractions.org/>)

# Annex G: PEP for patients after possible exposure to an infected health care worker

## Blood exposure incidents

1. Implementation of the recommendations in *HIV infected health care workers: Guidance on management and patient notification* (31) and in *Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: new healthcare workers* (33) will serve to minimise the risks that a patient may be exposed to the blood of an infected health care worker. Firstly, the restriction of HIV-infected health care workers from performing exposure-prone procedures minimises the likelihood of the health care worker sustaining an injury with the potential for transmission. Secondly, any health care worker who believes they may have been exposed to infection with HIV, in whatever circumstances, must promptly seek and follow confidential advice on whether they should be tested for HIV. Failure to do so may breach the duty of care to patients. Therefore health care workers are under a continual obligation to assess their own risk. New health care workers who will perform exposure-prone procedures are tested for HIV.
2. Four distinct scenarios can be envisaged that may result in a patient being exposed to HIV-infected blood from a health care worker or other patient:
  - during an exposure-prone procedure performed by a health care worker who does not know his/her HIV status;
  - during a non-exposure-prone procedure performed by an HIV-infected health care worker (e.g. physical assault on the health care worker, spontaneous nosebleed);

- where a health care worker accidentally sticks themselves with a needle and then puts the needle in the patient without realising what has happened; and
- in the unlikely event that an invasive device or product contaminated by use on one patient is accidentally re-used on another patient.<sup>6</sup>

Appropriate management of such potential exposure incidents will further reduce the risk of infection for patients.

3. The General Medical Council's guidance *Good Medical Practice* (39) (see Annex B) states that doctors infected with blood-borne viruses should not rely upon their own assessment of the risks they pose to patients. Any doctor is bound to take all proper steps to safeguard the interests of his/her patients and this would include ensuring that, following an exposure incident, he/she co-operates fully with those conducting the risk assessment, providing all necessary information about their own infection status or risk behaviour.
4. Every employer should draw up a policy on the management of blood exposure incidents. In accordance with guidance on the management of HIV-infected health care workers (31), each NHS body should designate one or more doctors<sup>7</sup> to whom health care staff or any other person present in the health care setting may be referred immediately for advice if they have been exposed, or have exposed others, to potentially infected blood. The designated doctor(s) needs to be of sufficient seniority (consultant level) and arrangements for adequate out-of-hours cover also need to be in place. Local policies should specify who will be responsible for provision of PEP

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6 Potential patient-to-patient transmissions should be assessed following usual guidance on source patient testing (see Section 2.3).

7 Examples include clinical specialists in Occupational Health, Public Health, Infectious Diseases and Microbiology. All need to be trained in conducting risk assessments and appropriate use of PEP.

and for the follow-up of staff or patients who have been exposed.

### Assessment of incidents

5. Circumstances that could allow the transmission of blood-borne viruses from health care worker to patient include:
  - visible laceration<sup>8</sup> occurring to a health care worker's hand in circumstances where the patient's open tissues or mucous membranes could be contaminated with the health care worker's blood;
  - visible bleeding of a health care worker from any other site (e.g. nosebleed) leading to significant bleed-back into a patient's open tissues or mucous membranes; and
  - an instrument or needle contaminated with the blood of the health care worker being inadvertently introduced into the patient's tissues.
6. Where any health care worker is involved in, or observes, any of the above incidents, that health care worker should take the following actions:
  - The injured person should stop the procedure as soon as reasonably practicable, wash and dress the wound and stem the bleeding.
  - Report the incident to the clinical supervisor or line manager or other person responsible according to local policies.
  - Ensure that, in accordance with local policy, the Occupational Health department, infection control officer or other nominated individuals are informed without delay.
  - Complete an accident/incident form.

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8 Most needlestick/puncture wounds would be excluded from consideration unless they resulted in significant bleed-back into the patient.

7. Local policies on recording critical incidents should be followed. In the surgical setting, it is good practice to record injuries to health care workers in operating theatre records and standard procedure for a preliminary risk assessment on the injured health care worker to be conducted by another member of the clinical team. This should include ascertaining whether visible blood is present that is likely or believed to be the health care worker's. Where the incident is not considered to be a significant blood exposure, this assessment must be recorded in the theatre record.
8. If, following a preliminary assessment, further risk assessment is warranted, this should be undertaken by the designated doctor (see paragraph 4 above) without delay to decide whether a significant exposure of the patient to the health care worker's blood has occurred. Where the incident is not considered by the designated doctor to be a significant blood exposure, no further action is required. The designated doctor's assessment should be entered in the health care worker's occupational health record and critical incident report if appropriate.
9. If the incident is considered to be a significant blood exposure, involving bleed-back into the patient, the injured health care worker should routinely be asked to consent to testing for HIV, hepatitis C and hepatitis B (where status not already known). Injuries resulting in overt bleeding will occur rarely. HIV testing of the health care worker should be conducted urgently, with the results available ideally within 8 hours of the exposure incident to maximise the benefit of PEP if indicated.<sup>9</sup>

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9 No PEP is currently available for hepatitis C. However, early treatment of acute hepatitis C infection may prevent chronic hepatitis C infection (53). Follow-up of exposed patients should follow that described in management for occupational exposure to hepatitis C (54). A course of hepatitis B vaccination with or without immunoglobulin may be recommended as PEP following exposure to hepatitis B (21).

10. Normalising the request to test for HIV (and hepatitis C) overcomes difficulties of making judgements about personal behaviour and risks and avoids stigmatising health care workers. The normal principles of confidentiality and informed consent apply. Pre-test discussion should cover both occupational and personal implications of a positive test result.
11. To encourage health care worker compliance with testing and reporting incidents, reporting policies should safeguard the health care worker's confidentiality (e.g. anonymised reports are adequate; the health care worker's identity should only be disclosed to those who need to manage the incident and the incident should be noted in their personal occupational health record).
12. If the health care worker tests positive for any blood-borne virus, the patient should be notified of an intra-operative exposure without revealing which member of the clinical team is infected. Incidents that entail informing patients should be reported to the National Patient Safety Agency. PEP for HIV (see 'Use of PEP' below) should usually only be offered and recommended following a positive test in the health care worker. Health care workers are presumed to be at low risk for HIV infection (55). There are also considerable practical difficulties in administering PEP in the immediate post-operative period (e.g. obtaining valid consent, possible need for parenteral administration and toxicity of PEP for sick patients). Only in exceptional circumstances (e.g. the health care worker is considered to be at high risk of HIV infection and/or refusal of the health care worker to be tested) would it be warranted to initiate PEP in the absence of a positive HIV test result.
13. If the health care worker tests negative for blood-borne viruses, there is no need to inform the patient about the incident and this would also avoid causing the patient unnecessary anxiety. A written record of the incident and

test results should, however, be entered in the health care worker's occupational health notes.

14. Where an incident occurs outside an exposure-prone setting involving a health care worker who is known to be HIV positive, the incident should be discussed in confidence by the designated doctor and the clinician responsible for the care of the patient. Where the clinician responsible for the care of the patient is also the injured health care worker, then another senior clinician should be consulted. These parties will make a decision about the management of the exposed patient. Where active management is indicated, the patient should be informed that an exposure may have occurred. The patient should then be managed in accordance with current guidelines for the management of exposure incidents to HIV-infected blood, including obtaining a baseline serum specimen from the patient for storage. This information should be recorded in the patient's notes.
15. Members of the infection control team should have access to confidential or anonymised copies of risk assessments performed following significant exposures for regular audit.

### Use of PEP

16. Where a patient has been accidentally exposed to the blood of a health care worker who is known or found to be HIV infected, then PEP is **recommended**. A 28-day course of treatment with a triple combination of antiretroviral drugs is normally used and needs to be commenced rapidly for maximum efficacy (see Section 3.3).
17. Particular consideration will need to be paid to the risk/benefit ratio of PEP for sick patients whose ability to tolerate antiretroviral therapy may be compromised. A higher threshold for commencing PEP may be appropriate because of the high incidence of side effects. Advice from an HIV specialist on the best combination to use may be necessary



for patients with systemic organ failure/organ insufficiencies. Advice on dose modification and formulations should be sought from an HIV specialist pharmacist.

### Follow-up of patients exposed to HIV-infected blood

18. The guidance on follow-up for health care workers occupationally exposed to HIV should be applied to all patients who suffer a significant exposure to known HIV-infected blood, regardless of whether they have received PEP (see Section 3.3).

### Special considerations

#### The health care worker who refuses a blood test

19. It would be unlawful to compel a health care worker to take a blood test. However, an employer may take appropriate steps to protect patients from a worker who refuses to undergo a test following an incident, such as thereafter restricting him/her from performing exposure-prone procedures.

#### The unconscious patient

20. PEP should not be withheld from an unconscious patient on the grounds that they are unable to consent, if clinical judgement deems it to be in their best clinical interests.

#### The nil-by-mouth patient

21. Antiretroviral drugs are available in a number of formulations suitable for naso-gastric or intravenous administration (see Table 1). Combinations of antiretrovirals for use as PEP in nil-by-mouth patients are therefore unlikely to differ significantly from standard currently recommended regimens (see Annex C).

**Table 1: Antiretroviral formulations suitable for naso-gastric or intravenous administration**

Drug	Strength	Route of administration <sup>1</sup>	Special requirements
<b>Nucleoside reverse transcriptase inhibitors</b>			
Abacavir oral solution	20mg/ml	Naso-gastric	HLA B*570 testing required beforehand and therefore not suitable
Didanosine tablets	200mg	Naso-gastric	Disperse in water. Adult dose >60kg is 2 tablets (400mg). Seek advice from pharmacist for other dosing
Emtricitabine oral solution	10mg/ml	Naso-gastric	Liquid has lower bioavailability than capsules therefore not equivalent mg for mg
Lamivudine oral solution	10mg/ml	Naso-gastric	
Stavudine powder for oral solution	1mg/ml	Naso-gastric	
Tenofovir tablet	245mg	Naso-gastric	Crush tablet and dissolve in 100ml water (may take up to 20 minutes to dissolve). Administer immediately
Truvada tablet	245mg tenofovir and 200mg emtricitabine	Naso-gastric	Crush tablet and dissolve in 100ml water (may take up to 20 minutes to dissolve). Administer immediately
Zidovudine oral syrup	50mg/5ml	Naso-gastric	
Zidovudine injection	10mg/ml	Intravenous	

Drug	Strength	Route of administration <sup>1</sup>	Special requirements
<b>Protease inhibitors<sup>2</sup></b>			
Fosamprenavir oral solution	50mg/ml	Naso-gastric	
Lopinavir with ritonavir oral solution	Lopinavir 400mg and ritonavir 100mg in 5ml	Naso-gastric	
Ritonavir oral solution	400mg/5ml	Naso-gastric	
<b>Non-nucleoside reverse transcriptase inhibitors<sup>3</sup></b>			
Nevirapine oral suspension	10mg/ml	Naso-gastric	
Efavirenz oral liquid	30mg/ml	Naso-gastric	Liquid has lower bioavailability than capsules therefore not equivalent mg for mg

Notes: 1. Data are limited on adsorption via naso-gastric route for all drugs mentioned.

2. No stability data available on administering atazanavir via naso-gastric route.

3. See Annex C paragraph 11 for caveats around the use of non-nucleoside reverse transcriptase inhibitors.

## Annex H: Summary of evidence on maximum interval between exposure and commencing PEP

1. In the absence of randomised studies addressing the interval between a risk incident and initiation of PEP, three lines of evidence provide guidance: (i) animal studies; (ii) human perinatal transmission studies; and (iii) consideration of virological/immunological studies on the natural history of primary infection.
2. Firstly, the ability of PEP to prevent infection has been studied in the macaque animal model. Thus, infection of this species with simian immunodeficiency virus (SIV) through the intravenous route, or HIV-2 through the intravaginal route, was shown to be prevented when tenofovir was administered subcutaneously within 12 hours of infection and continued for 28 days (56–58). When treatment was delayed by 48 or 72 hours in the SIV/macaque experiments, only a proportion of animals were protected from infection. Further, a treatment duration of 3 or 10 days, rather than 28 days, was also associated with reduced levels of protection. By contrast, in one study, PEP with intravenous zidovudine, lamivudine and indinavir as early as 4 hours post-infection in an SIV/HIV chimera (SHIV) infection of macaques did not prevent infection (59).
3. One human perinatal transmission intervention study is also informative. In a subset of participants in the ACTG 076 protocol, where antenatal treatment of the pregnant woman with zidovudine was omitted (through choice or limited clinical care), neonatal zidovudine started within 48 hours of birth was associated with an HIV transmission rate of 9.3%, compared with a rate of 18.4% when zidovudine was started at a later time (60).

4. Recent studies of the SIV-macaque model, as well as natural history studies following HIV-1 transmission in humans, demonstrate extensive infection of gut-associated CD4 lymphocytes, and their preferential depletion is evident at the time of primary infection. This suggests there is only a brief window of opportunity to prevent or abort infection (through administering PEP) before irreversible systemic infection and HIV seroconversion occur (61; 62).
5. Together, these studies provide some evidence that PEP is most likely to be effective when initiated as soon as possible (within hours, and certainly within 48–72 hours of infection), and continued for at least 28 days. It should be noted that the evidence base on which these conclusions are based is limited.

# Annex I: EAGA PEP Working Group membership

## EAGA Members

Dr Andrew Freedman (Chair)

Senior Lecturer/Hon. Consultant in Infectious Diseases, Cardiff University School of Medicine, Cardiff

Mr Nick Partridge

Chief Executive, Terrence Higgins Trust, London

Professor Deenan Pillay

Professor of Virology, University College London and Health Protection Agency, London

Dr Anton Pozniak

Consultant Physician in HIV/GUM, Chelsea and Westminster Hospital, London

Dr Alison Rimmer

Consultant Occupational Physician, Sheffield Occupational Health Service, Sheffield

## Co-opted Members

Dr Valerie Delpech/Dr Barry Evans

Consultant Epidemiologist, HIV/STI Department, HPA Centre for Infections, London

Dr Fortune Ncube

Surveillance of Significant Occupational Exposure to Bloodborne Viruses in Healthcare Workers, HPA Centre for Infections, London

Ms Louise Brown

Service Improvement Lead, Whittall Street GUM Clinic, Birmingham

Ms Rosy Weston  
Pharmacy Team Leader HIV and Sexual Health, Imperial College  
Healthcare NHS Trust, London

### **Department of Health officials**

Mr Gerry Robb  
EAGA Sponsor, Infectious Disease and Blood Policy Branch,  
Department of Health

Ms Kay Orton  
Sexual Health Programme, Department of Health

### **Secretariat**

Dr Linda Lazarus  
Expert Advice Support Office, Health Protection Agency, London

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# HIV for non-HIV specialists



## Diagnosing the undiagnosed

by Dr Rachel Baggaley

A practical guide for healthcare professionals in secondary care to support improved detection and diagnosis of HIV in the UK



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By Dr Rachel Baggaley

**MEDICAL FOUNDATION FOR AIDS  
& SEXUAL HEALTH (MedFASH)**

A charity supported by the British Medical Association



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<b>Introduction</b>	<b>5</b>
Foreword	5
Preface	7
<b>1 HIV in the UK: an overview</b>	<b>9</b>
Background	10
Undiagnosed HIV	11
Late diagnosis	11
The natural history of HIV infection	13
<b>2 Recommendations for testing</b>	<b>17</b>
Who can perform an HIV test?	18
Who should be recommended an HIV test?	18
Which test to use?	20
How often to test?	21
How to offer an HIV test	22
<b>3 How to diagnose HIV in non-HIV specialist secondary care settings</b>	<b>25</b>
3.1 Acute and emergency medicine	26
3.2 Respiratory medicine	29
3.3 Neurology and psychiatry	33
3.4 Dermatology	35
3.5 Gastroenterology and hepatology	37
3.6 Oncology	39
3.7 Obstetrics and gynaecology	40
3.8 Haematology	41
3.9 Ophthalmology	42
3.10 Ear, nose and throat	43
3.11 Other presentations where HIV testing should be routinely offered	44
3.12 Paediatrics	46

# CONTENTS

<b>4 Pre-test discussion</b>	<b>49</b>
Written consent	51
Patients who decline a test	51
<b>5 Post-test discussion</b>	<b>53</b>
Post-test discussion for individuals who test HIV-negative	54
Post-test discussion for individuals who test HIV-positive	55
Non-attendance for HIV test results	57
Providing written confirmation of results	58
<b>6 Barriers to HIV testing</b>	<b>59</b>
Patient concerns about HIV testing	60
Clinicians' concerns about HIV testing	64
Working with groups most at risk of HIV infection	66
<b>7 Annexes</b>	<b>71</b>
Annexe A: Advice on testing without consent	72
Annexe B: Post-exposure prophylaxis (PEP)	73
Annexe C: The patient diagnosed very late	75
<b>8 Useful sources of further information</b>	<b>77</b>
Websites for clinicians	78
Websites for patients	79
Leaflets for patients	79
Organisations for support and information	80
<b>9 References</b>	<b>83</b>
<b>10 Subject index</b>	<b>89</b>

**Followed by: The British Association for Sexual Health and HIV (BASHH),  
British HIV Association (BHIVA) and British Infection Society (BIS)**  
***UK National Guidelines for HIV Testing 2008***

# Foreword

**Much has changed in the field of HIV in the UK. A diagnosis of HIV used to be considered a death sentence, but over the past decade there have been major advances in the management of HIV-related conditions.**



Dr Mary Armitage

Care by a specialist team, including the use of antiretroviral therapy, has transformed the outlook for many patients, for most of whom HIV may now be considered a chronic disease. However, early diagnosis and management contribute substantially to this improvement in prognosis whereas those who are diagnosed late have greatly increased morbidity and mortality.

It has been estimated that over 73,000 people have HIV in the UK, yet nearly a third of these are undiagnosed. Over the past five years there have been more than 7,000 new diagnoses per year, and around one third are late. Furthermore, delayed diagnosis accounts for at least 35 per cent of HIV-related deaths. Early diagnosis reduces the risk of onward transmission, both because effective treatment itself reduces infectiousness and because diagnosis allows modification of behaviour to reduce the risk.

Yet many patients who are diagnosed late have been seen previously in other parts of the healthcare system. Opportunities to make an earlier diagnosis were missed. Why are we failing to diagnose HIV, and how can we improve the care that patients should be receiving? It is true that HIV is not always easy to diagnose – many of the symptoms are vague or non-specific. Patients with HIV-related symptoms and signs can present in any secondary care setting and to a range of non-HIV specialists who may not see many cases and have a low index of suspicion. These difficulties are compounded by the historical perception that HIV testing is different, difficult and not part of routine testing when considering differential diagnoses. Clinicians may feel reluctant to raise the possibility of what is still seen as a stigmatising diagnosis, and they may have concerns about exceptional requirements for secrecy. They may find it difficult to initiate the discussion, or believe that special counselling skills are required.

In 2007, a letter from the Chief Medical and Nursing Officers highlighted the importance of improving the detection and diagnosis of HIV. The Department of Health has funded a range of activities to increase the rates of diagnosis and to de-stigmatise HIV, and this booklet from the Medical Foundation for AIDS & Sexual Health (MedFASH) is part of the strategy. During my term as Clinical Vice President of the Royal College of Physicians, I had the opportunity to work collaboratively with BHIVA, BASHH and BIS, resulting in establishing standards for HIV services, and I was delighted to be invited by MedFASH to chair the Advisory Group to develop guidance for non-HIV specialists.

We wanted to produce practical help and advice to raise awareness amongst non-HIV specialists, to reduce barriers to testing and to ensure that HIV testing becomes routine. The booklet provides an overview of the many common presenting conditions when generalists should consider a diagnosis of HIV and strategies for approaching the offer of an HIV test. We were fortunate that our project coincided with the production of updated guidelines for carrying out HIV testing in all healthcare settings, led jointly by BHIVA, BASHH and BIS. We have worked together to ensure that the two pieces of work complement and support each other.

I would like to thank the members of the Advisory Group who have given so much time and expertise, and also Russell and Ruth from MedFASH for their enthusiasm and hard work in support of the project. Our aims are to reduce levels of undiagnosed HIV and to increase earlier diagnoses, and we hope that this booklet will help to achieve these outcomes.

A handwritten signature in blue ink that reads "Mary Armitage". The signature is written in a cursive style with a large initial 'M' and a long, sweeping tail on the 'e'.

**Dr Mary Armitage BSc, MBChB (hons), DM, FRCP, FRCPE,  
Immediate Past Clinical Vice-President, Royal College of Physicians.**

# Preface

## About this booklet

This booklet is one in a series of practical tools to explain the rationale and promote the need for increased HIV testing in all clinical settings to help reduce the level of undiagnosed HIV infection in the UK, and to improve communication about patients with HIV between health professionals who share their care. It is based on the successful MedFASH booklet, HIV in Primary Care, by Dr Sara Madge, Dr Philippa Matthews, Dr Surinder Singh and Dr Nick Theobald.

It is designed to complement the *UK National Guidelines for HIV Testing 2008* published by the British Association for Sexual Health and HIV (BASHH), British HIV Association (BHIVA) and the British Infection Society (BIS). It should be noted that the guidelines are intended for practitioners in all healthcare settings and therefore some of the recommendations in them are more applicable to primary care than secondary care. For information about HIV diagnosis and testing in primary care, please refer to Madge et al mentioned above.

The focus of this booklet is on HIV testing and diagnosis and it is aimed specifically at non-HIV specialist clinicians working in secondary care settings who are likely to encounter undiagnosed HIV in patients either in specialist outpatient clinics, or who are admitted to hospital as inpatients to general medical wards via their GP or via the emergency department. The booklet provides supplementary information to that given in the guidelines, as well as case studies and concrete strategies to assist non-HIV specialist clinicians in detecting undiagnosed HIV and implementing HIV testing in their daily practice. For ease of use the guidelines are reprinted in their entirety at the back of this booklet.

## About the author

Dr Rachel Baggaley is Head of HIV at Christian Aid, a UK based development agency which supports more than 250 HIV projects in 40 developing countries. She is also an honorary research fellow at the London School of Hygiene and Tropical Medicine and works one day a week in a clinic in South London. Previously she spent six years working on HIV programmes in Zambia and then for the World Health Organization in Geneva on guidelines for antiretroviral therapy in developing countries, HIV testing and counselling and the prevention of mother-to-child transmission.

## **About the Medical Foundation for AIDS & Sexual Health (MedFASH)**

MedFASH is a charity supported by the British Medical Association. It works with policy-makers and health professionals to promote excellence in the prevention and management of HIV and other sexually transmitted infections. Recent work includes a review of GUM services in England, managing the development of the Royal College of General Practitioners' Introductory Certificate in Sexual Health and undertaking a review of the *National strategy for sexual health and HIV* for the Independent Advisory Group on Sexual Health and HIV.

Comments about this booklet are welcome, and will inform future editions. Please send them to the Medical Foundation for AIDS & Sexual Health.

Whilst all reasonable efforts have been made to ensure the information contained in this booklet is accurate, no representations or warranties are made (whether expressed or implied) as to the reliability or completeness of such information. Neither the Medical Foundation for AIDS & Sexual Health nor the author can be held liable for any consequence or loss arising directly or indirectly from the use of, or any action taken in reliance on, any information appearing in this booklet.

# SECTION 1

## HIV in the UK: an overview

### IN THIS SECTION

Background	10
Undiagnosed HIV	11
Late diagnosis	11
The natural history of HIV infection	13



# HIV in the UK: an overview

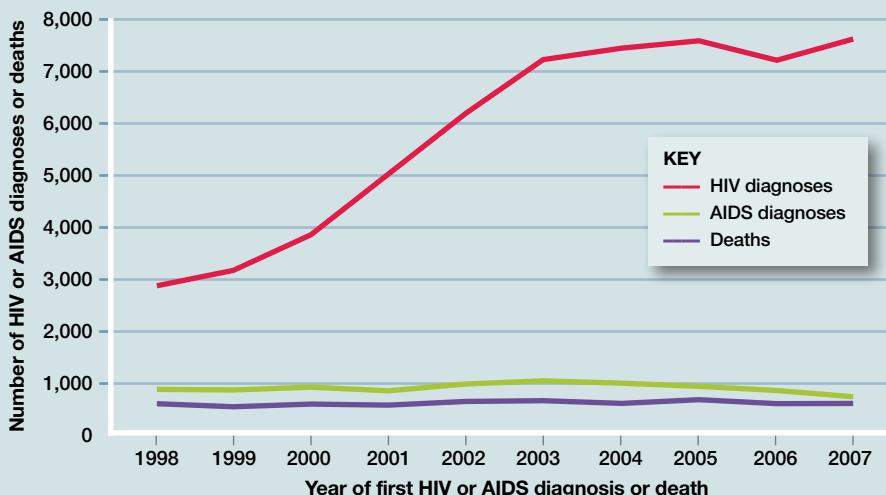
## Background

Human immunodeficiency virus (HIV) is one of the most important communicable diseases in the UK. There were an estimated 73,000 people living with HIV infection in the UK at the end of 2006<sup>1</sup>. Annual numbers of new HIV diagnoses in the UK more than doubled between 1997 and 2003 (from 2,768 to 7,350), and have increased more slowly since then to reach a peak of 7,734 in 2007<sup>2</sup>.

There has been effective treatment for HIV since the mid 1990s. Antiretroviral therapy (ART) and other interventions have resulted in a dramatic reduction in the number of HIV-related deaths in the UK, and most infected people in the UK are living with HIV as a chronic condition rather than an inevitably fatal illness.

Over the past decade there has been a rapid increase in the number of HIV infections diagnosed in the UK which were acquired through

**Figure 1: First HIV and AIDS diagnoses in the UK, and deaths among HIV infected individuals 1998 to 2007**



Source: Health Protection Agency Centre for Infections. Data to end June, 2008.

heterosexual sex (see figure 2), and these account for just over half of all new diagnoses annually. Of these, the majority were acquired abroad, mostly attributable to exposure in sub-Saharan Africa. African-born men and women made up 35 per cent of all adults with HIV in the UK in 2006, and accounted for 68 per cent of all heterosexually acquired infections.

There are still high levels of HIV transmission in men who have sex with men (MSM) and since 2001 the number of HIV diagnoses reported annually has consistently exceeded the annual number of diagnoses throughout the 1990s. It is believed that 83 per cent of these men acquired their infection in the UK.

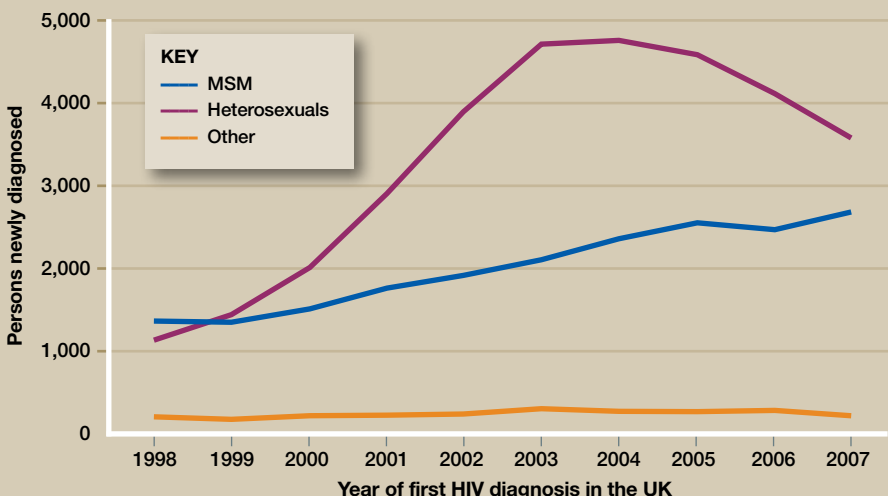
## Undiagnosed HIV

It is believed that at the end of 2006 about 21,600 HIV-infected people aged 15-59 remained undiagnosed in the UK, approximately a third of the total infected<sup>1</sup>. Of these undiagnosed adults, 43 per cent were estimated to be men who have sex with men (MSM), 51 per cent heterosexuals (mostly African-born), and 5 per cent injecting drug users.

## Late diagnosis

HIV-related morbidity and mortality are increasingly concentrated among those who are diagnosed late. Although many of these patients will do well, some will be left with permanent disability and many will take longer

**Figure 2: First HIV diagnoses in the UK by exposure category 1998 to 2007**



Source: Health Protection Agency Centre for Infections. Data to end June, 2008.

to respond well to treatment<sup>3</sup>. Early diagnosis is also more cost-effective as timely initiation of ART leads to fewer episodes of acute serious illness<sup>4</sup>.

A recent audit of deaths caused by HIV among adults reported that in approximately 25 per cent of cases diagnosis occurred too late for optimal treatment (and that late diagnosis accounted for 35 per cent of HIV-related deaths)<sup>5</sup>. This highlights the need to improve diagnosis of HIV by increasing the uptake of HIV testing. There is also evidence that a significant proportion of people who are diagnosed late with HIV have been seen by healthcare professionals at some point in the year previous to diagnosis with what were, in retrospect, HIV-associated symptoms but were not offered an HIV test<sup>6</sup>.

see page 14 for  
the CD4 count

The Health Protection Agency (HPA) currently defines late diagnosis as having a CD4 cell count at diagnosis of less than 200 cells/mm<sup>3</sup>. However if late diagnosis is defined as having a CD4 count less than 350 cells/mm<sup>3</sup> (ie below the threshold currently recommended for starting ART) this figure rises to 57 per cent.

In late 2007 the UK's four Chief Medical Officers (CMOs) and Chief Nursing Officers (CNOs) wrote to all doctors and nurses setting out good practice to improve the detection and diagnosis of HIV in non-HIV specialist settings and reminding them of the need to consider offering an HIV test, where clinically indicated<sup>7,8,9,10</sup>. This is in line with international recommendations from the World Health Organization (WHO)<sup>11</sup>. In the USA the Centers for Disease Control and Prevention (CDC)<sup>12</sup> have recommended that screening for HIV infection should be performed routinely for all patients aged 13-64 years in all healthcare settings. Because the UK's overall HIV prevalence is approximately 0.1 per cent it is unlikely that routine screening of the whole population on the US model will be adopted on grounds of cost-effectiveness as HIV in the UK is concentrated in distinct population sub-groups.

Many clinicians believe that discussing HIV with patients is difficult, or that patients need 'pre-test counselling' by a trained counsellor. This is not the case and this was highlighted by the UK CMOs' Expert Advisory

Group on AIDS as long ago as 1996 in guidelines on pre-test discussion for HIV testing<sup>13</sup>. This cautious approach to offering an HIV test is a legacy of a time when the prognosis for those infected with HIV was poor and treatment options were limited. Since the mid-1990s, ART has transformed long-term health outcomes for people with HIV, although no cure is as yet available.

However, HIV remains a highly stigmatised health condition in the UK

## The case for earlier diagnosis

57 per cent of people with HIV in the UK are diagnosed at a late stage.

This results in:

- a worse prognosis with significantly increased risk of permanent disability
- a significant increase in mortality
- ongoing transmission to sexual partners.

Most people diagnosed late will have had prior contact with healthcare workers.

**The case for routine HIV testing**

- HIV testing should be seen as a normal part of the diagnostic process and a duty of care
- Where routine HIV testing is in place, uptake of testing is increased
- The exceptional approach to HIV testing has been a barrier to clinicians in offering testing and to patients in accessing it
- ‘Normalising’ HIV testing will help to reduce stigma
- Failure to diagnose HIV leads to avoidable deaths and serious illness
- Effective HIV treatment reduces infectiousness and can reduce onward transmission

and this often deters people from actively seeking a test, as well as deterring clinicians from offering one. While there are clear individual and public health<sup>14,15</sup> benefits to offering HIV testing, and it should be offered and recommended to everyone who could have been exposed to HIV infection, clinicians need to be aware that patients may have reservations about being tested for HIV and these are discussed later in the booklet.

**The natural history of HIV infection**

HIV is a retrovirus which preferentially infects immune system cells, particularly the CD4 lymphocytes. It is present in an infected person’s blood, and is also present in other body fluids, such as semen, vaginal secretions, rectal secretions and breast milk.

**The ‘window’ period**

Antibodies to HIV typically appear between four to six weeks after infection, but this may take as long as 12 weeks. This is commonly referred to as the ‘window’ period. During this period an HIV

antibody test will not detect the infection but the virus is still present. The p24 antigen is a protein of the virus itself and can be detected in a blood sample for a short period after infection (normally from two to five weeks). However, it rapidly becomes undetectable once antibodies to HIV start to develop. It is therefore useful in identifying early HIV infection but not for established infection.

**Primary HIV infection or seroconversion**

The patient may experience a flu-like illness at the time of infection. Symptoms develop in over 60 per cent of people at this stage. They may be mild and non-specific, but they can also be marked and precipitate a referral to secondary care or a visit to the emergency department.

**Stages of HIV infection**

**Asymptomatic stage**

Once the symptoms of primary HIV infection subside, the asymptomatic stage of the infection begins. There are usually no overt clinical signs and symptoms of HIV infection during this stage and the individual with HIV may be well for some or many years with a CD4 count of over 500 cells/mm<sup>3</sup>. Some laboratory tests may be abnormal, eg anaemia, neutropenia, lymphopenia, thrombocytopenia, and diffuse hypergammaglobulinaemia.

The CD4 count declines at a rate of approximately 40-80 cells/mm<sup>3</sup> per



year in untreated individuals, but some progress faster than others. There is wide variation in the time it takes to progress from primary infection to symptomatic disease (see figure 3).

## Symptomatic stage

If untreated, infection with HIV results in the development of HIV-associated or opportunistic infections (OIs). Fungi, viruses, bacteria and other organisms that are usually harmless can all cause OIs. Some, eg candidiasis (oral and/or vaginal), are more common in the immunocompromised. Others, eg *Pneumocystis pneumonia* (PCP) only cause infection in the immunocompromised.

Constitutional symptoms may occur. These include fevers, night sweats, headache, malaise, fatigue, diarrhoea and weight loss. Generalised lymphadenopathy involving extra-inguinal sites may be present.

Other conditions may occur including oral hairy leukoplakia, shingles, recurrent herpes simplex outbreaks and episodes of seborrhoeic dermatitis, folliculitis and psoriasis.

Bacterial infections (most commonly *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Staphylococcus aureus*) may occur during this stage, leading to sinusitis, bronchitis and pneumonia.

## Symptomatic (AIDS-defining)

Some infections and malignancies are associated with HIV infection and their diagnosis classifies an HIV-infected patient as having developed AIDS. Other conditions including neurological disease associated with HIV and excessive weight loss (more than 10kg) may also lead to an AIDS diagnosis.

Later stages of infection are associated with infections including PCP, cytomegalovirus (CMV), progressive multifocal leucoencephalopathy (PML), *Mycobacterium avium-intracellulare* (MAI), cryptococcosis, cryptosporidiosis, toxoplasma encephalitis, and oesophageal candidiasis. Individuals are also at increased risk of malignancies including Kaposi's sarcoma (KS), non-Hodgkin's lymphoma and malignancies of the cervix and anus associated with human papilloma virus (HPV).

## Diagnostic markers

### CD4 count

The CD4 lymphocyte count is a useful indicator of the degree of immunosuppression in those infected with HIV. In healthy, non-HIV-infected individuals the CD4 count is usually above 500 cells/mm<sup>3</sup>, although some individuals have naturally lower CD4 counts. It is normal for CD4 counts to be variable. Trends are therefore more important than single readings. Patients with a CD4 count of below 200 cells/mm<sup>3</sup> are at risk of HIV-related opportunistic infections and tumours, but some may not have significant symptoms.

see page 20 for the different HIV tests

The CD4 count is a valuable clinical tool in deciding when to start antiretroviral therapy (ART) and when to commence prophylaxis against opportunistic infections.

## Viral load

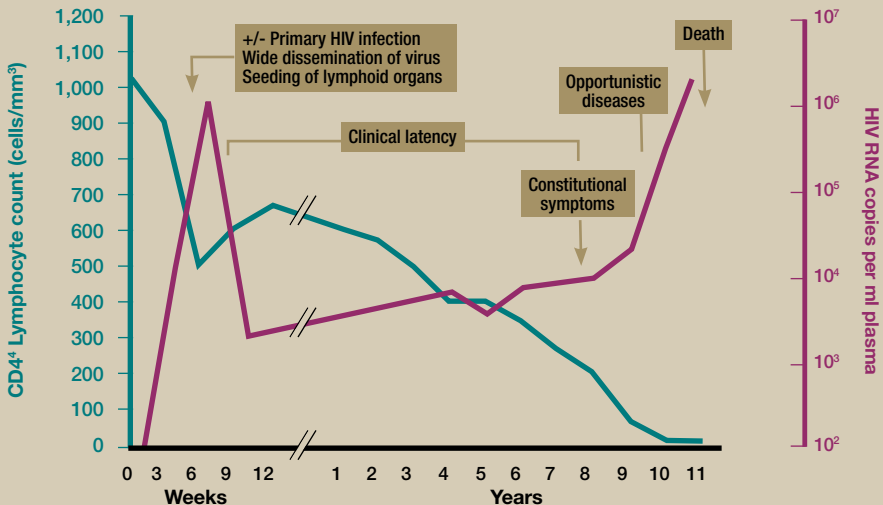
This is a measure of the amount of HIV in the blood. Viral load can range from undetectable to over a million copies/ml.

The degree of viral replication is linked to the rate of CD4 decline, and hence disease progression. The aim of ART is to reduce viral load to undetectable levels. A rising viral load in a patient on ART can indicate a range of problems, eg drug resistance may be developing or the patient may not be adhering to their treatment regimen.

## How the CD4 count and viral load interrelate

If HIV is replicating at high levels the viral load predicts a more rapid CD4 decline. The CD4 count of patients not taking ART who have a high viral load is likely to fall more rapidly than that of those with a lower viral load. Once the viral load is suppressed CD4 counts recover with a decreased risk of developing OIs, tumours and other complications of HIV infection (see figure 3).

**Figure 3. Association between virological, immunological, and clinical events and time course of HIV infection**



Adapted from: Fauci AS. *Ann Intern Med.* 1996 Apr 1; 124 (7):654-63 (with permission)



# SECTION 2

## Recommendations for testing

### IN THIS SECTION

<b>Who can perform an HIV test?</b>	<b>18</b>
<b>Who should be recommended an HIV test?</b>	<b>18</b>
<b>Which test to use?</b>	<b>20</b>
<b>How often to test?</b>	<b>21</b>
<b>How to offer an HIV test</b>	<b>22</b>



# Recommendations for testing

## Who can perform an HIV test?

People with undiagnosed HIV may potentially be seen in any hospital outpatient clinic or ward, and offering HIV testing to patients should be considered during any clinical contact. With forethought and preparation, it is within the competence of all clinicians and appropriately trained healthcare workers to obtain consent for and perform an HIV test. There is no need for special counselling skills beyond those required for routine clinical practice.

## Who should be recommended an HIV test?

HIV testing has historically been managed on an 'opt-in' basis, ie levels of uptake have been determined by patients actively coming forward for testing. However, the positive experience of offering HIV testing as routine to all patients attending antenatal services and in larger urban areas to all patients attending GUM services, demonstrates that offering HIV testing on an 'opt-out' basis, ie as a routine investigation, increases the likelihood of patients agreeing to test.

The *UK National Guidelines for HIV Testing 2008* from BASHH, BHIVA and BIS recommend that HIV testing is made routine under the following circumstances.

### **Routine HIV testing for all people attending specific services**

It is recognised that with some clinical services there is a potentially increased HIV prevalence amongst attendees and compelling reasons exist to identify HIV early. Such services include:

**GUM or sexual health clinics.** Risk factors for sexually transmitted infections are the same as those for HIV infection and in GUM settings it is standard policy to include an HIV test routinely within the full sexual health screen.

**Antenatal services.** Since the introduction of the universal recommendation of antenatal HIV testing in the UK in 1998, the mother-to-child transmission rate has remained below 2 per cent<sup>16</sup>.

**Termination of pregnancy services.** There is evidence from unlinked anonymous seroprevalence surveys conducted in inner London termination clinics that there is a higher prevalence of HIV infection in women terminating their pregnancies compared with those giving birth.

**Drug dependency programmes.** Injecting drug use is a recognised risk factor for HIV infection and undiagnosed HIV prevalence among injecting drug users was 39 per cent at the end of 2006<sup>1</sup>.

**Services for patients with tuberculosis, hepatitis B/C and lymphoma.** There is an increased risk of HIV infection in patients with these conditions. Treatment for these conditions may therefore have to be changed for patients in these groups.

**Dialysis, blood donation and organ transplant services.** Patients with chronic kidney disease (CKD) are routinely screened for HIV infection before initiation of dialysis<sup>17</sup>. It is standard practice to test anyone who is being put forward for a transplant for HIV, as it is for anyone donating blood or tissues/organs.

Other services not mentioned in the guidelines, but where routine HIV testing of all patients would be good practice are:

**Services for patients requiring immunosuppressant therapy.** Immunosuppressant therapy in a patient already immunocompromised by undiagnosed HIV risks unforeseen complications<sup>18</sup>.

**Haemophilia services.** In the UK blood for transfusion has been screened and blood products heat-treated for HIV since the mid 1980's, but patients who have received treatment from countries where screening procedures are not in place should be offered HIV testing.

**Services for victims of rape.** The acute situation should be managed by specialist services. All victims of rape should be offered full screening for STIs including HIV and offered post-exposure prophylaxis (PEP) if appropriate.

**Services for people who have occupational exposure to blood or blood products.** All healthcare settings should have clear guidelines, referral and support procedures for this eventuality as detailed in the DH guidelines on post-exposure prophylaxis (PEP) following occupational exposure<sup>19</sup>.

**Services for people requesting post-exposure prophylaxis following sexual exposure (PEPSE).** The BASHH guideline for the use of PEPSE stipulates that it is mandatory to test individuals for whom PEPSE is provided, using a test with rapid result, prior to or shortly after commencing therapy to prevent inadvertent and unplanned treatment of pre-existing undiagnosed HIV infection<sup>20</sup>.

**Routine HIV testing for all people who present for healthcare where HIV enters the differential diagnosis**

Some conditions, eg Kaposi's sarcoma and CMV retinitis, are highly associated with HIV infection and their presence should prompt HIV testing. Other conditions indicating a need for HIV testing include tuberculosis, hepatitis B/C and lymphoma.

Many of the problems associated with HIV are also observed in people without HIV infection, eg seborrhoeic dermatitis, herpes zoster and folliculitis. However, these are more common in the HIV-infected and they are more likely to be recurrent or slow to resolve. It is therefore recommended that HIV should enter the differential diagnosis in these instances and testing should be performed.



see page 44 in section 3.11 for signs of primary HIV infection

Glandular fever-like illnesses are associated with HIV seroconversion (primary HIV infection) and should therefore prompt testing.

## **Routine HIV testing for all people who belong to a group at higher risk of HIV infection**

People from populations at higher risk of HIV infection may attend clinical services other than those mentioned above. The *UK National Guidelines for HIV Testing 2008* recommend they be offered an HIV test routinely.

Risk should be discussed without pre-judgement. These groups are:

- all individuals diagnosed with a sexually transmitted infection
- all individuals with a current or former sexual partner with HIV
- all men who have sex with men
- all female sexual contacts of men who have sex with men
- all individuals who report a history of injecting drug use
- all individuals from countries of high HIV prevalence\*
- all sexual contacts of individuals from countries of high HIV prevalence.\*

\*A table ranking countries by adult HIV prevalence rates can be found online at <http://www.unaids.org/en/KnowledgeCentre/HIVData/Epidemiology/latestEpiData.asp><sup>21</sup>.

It is also useful to consider routine HIV testing for the following:

- all individuals with a current or former sexual partner with a history of injecting drug use
- all individuals who have received injections, blood transfusions, blood products, transplants or other risk-prone healthcare-related procedures in countries without rigorous programmes of equipment sterilisation, screening of blood, organs and tissues or treatment of blood products.

## **Routine HIV testing in areas where the diagnosed HIV prevalence exceeds 2 in 1,000**

The US experience of offering universal HIV testing to all people presenting for healthcare aged between 13 and 64 recognises that screening is only cost-effective in areas where the prevalence of undiagnosed HIV exceeds 1 in 1,000<sup>12</sup>. As undiagnosed prevalence in the UK is half that of diagnosed prevalence, the *UK National Guidelines for HIV Testing 2008* recommend offering routine HIV testing to the following patients in an area where diagnosed HIV prevalence in the local population (PCT or Local Authority) exceeds 2 in 1,000:

- all men and women registering in primary care
- all general medical admissions.

## **Which test to use?**

### **Laboratory testing**

The most commonly used test looks for both the HIV-1 and HIV-2 antibody and the HIV p24 antigen. This is an improvement on the previous

generation of HIV tests which looked for antibodies only, and can give a reliable result from as little as 28 days after exposure. In the event of a positive result a second sample is requested for confirmation.

HIV RNA quantitative assays are a form of Nucleic Acid Amplification Test (NAAT). These are not often used as an initial diagnostic test for HIV in adults as they are expensive and have a high false positivity rate. However they may be offered in special circumstances, eg following recent potential exposure where post-exposure-prophylaxis is being considered, and are now the preferred test to diagnose early infection if primary HIV infection is suspected and the antibody/antigen test is negative.

### **Point of care testing**

Point of care testing uses rapid testing devices which look for antibodies only, but they have the advantage that a test result can be given within 15 minutes of the specimen being taken and the result can be delivered at the initial consultation. The specificity of rapid testing devices is lower than that of the standard laboratory tests. In low prevalence settings this may result in a significant number of false positive results. It is therefore essential that all positive point of care test results are confirmed with a conventional blood test. The British Association for Sexual Health and HIV (BASHH) has produced a guideline on point of care testing<sup>22</sup> which suggests the use of rapid testing devices may be suitable for:

- GUM clinics
- obstetric settings for high-risk patients
- PCT-run community clinics
- outreach settings
- source patient testing prior to post-exposure prophylaxis (PEP) for both occupational and sexual exposure
- individuals presenting for post-exposure prophylaxis following sexual exposure (PEPSE) to prevent inadvertent and unplanned treatment of pre-existing undiagnosed HIV infection.

Rapid testing devices may also be purchased via internet sites and there are anecdotal reports of people self-testing. People who purchase internet tests may not fully understand their limitations in terms of sensitivity and specificity, and may be unaware of the need to confirm results and the need for re-testing if within the window period.

The national *Standards for HIV Clinical Care* (2007) recommend that all patients who test positive in any setting are booked into a specialist HIV clinic within 14 days of diagnosis to have their results confirmed and for further assessment and management<sup>23</sup>.

### **How often to test?**

Because of the time taken for antibodies to appear, repeat testing should be offered as a precaution to anyone who is at risk from recent exposure and is within the 'window' period. Although this can be as little as a month

see page 13 for  
more on the  
window period

if a fourth generation assay which detects both antibody and antigen is used, the window period is considered to be three months.

Annual testing can be offered to those at high risk from infection such as men who have sex with men (MSM), injecting drug users or sexual partners of people with HIV.

Because of the success of universal antenatal screening, it is recommended to repeat the offer of testing for women in antenatal clinics who refuse testing at booking. Repeat testing at 34-36 weeks' gestation should also be considered for women who initially test negative but have risk factors<sup>24</sup> such as a partner with HIV, because the high viral load associated with primary infection correlates with a high risk of HIV transmission from mother to child.

A point of care test should be recommended to women presenting to services for the first time in labour, as even at that stage preventive treatment can be given to reduce the risk of mother-to-child transmission.

see page 64 for  
clinicians barriers  
to HIV testing

### How to offer an HIV test

Clinicians may find it difficult to raise the issue of HIV testing with a patient. Here are some suggested approaches to broaching the subject.

When an HIV test is indicated by clinical symptoms, or by the diagnosis of an illness which could be attributable to a weakened immune system, the most straightforward way to approach the subject of a test is simply to state that an HIV test is recommended when these symptoms or conditions are present.

Examples of ways to phrase this are: 'These symptoms are usually caused by viral infections. While there are many viruses we can't test for, it's important to rule out the ones we can test for. HIV is one of these,' or 'I have no idea if you are at risk of HIV infection and I'm not making any assumptions but your symptoms suggest a weakened immune system and I'd like to make sure that I haven't missed anything'.

Similarly, in an antenatal clinic the midwife could say: 'We always recommend HIV testing for pregnant women because for mothers with HIV we can provide treatment to prevent them passing HIV to their babies'. In a dialysis unit the clinician could state: 'We routinely screen everyone in this clinic for HIV and for hepatitis B and C before starting treatment'. In a dermatology outpatient clinic a clinician might say: 'We always screen for HIV in patients who have shingles, because very occasionally this can be associated with HIV and we want to make sure that we don't miss anything'.

Offering and recommending testing to patients from groups at higher risk of HIV infection and who are attending healthcare services for reasons which are ostensibly or, in fact, unrelated to HIV can be more difficult as the patient may not be expecting to hear this. Consider the case of a man from Malawi presenting at the emergency department with a broken ankle;

### **Omission of sexual history taking should not prevent HIV testing**

- If a clinician believes that HIV may be part of a differential diagnosis, HIV testing should be recommended whether or not a sexual history is taken.

HIV testing may be the last thing he wants to think about or considers relevant to his needs at the time.

Nonetheless, where there are good epidemiological reasons for recommending testing to patients from higher-risk groups, the subject can be raised by stating that clearly and without judgement: 'I realise this might

not be the first thing on your mind, but have you considered an HIV test? I ask because we know that there is a high rate of HIV among gay men/people from [country of high prevalence] and we want to make sure that anybody who needs it gets the care they need as early as possible.'

It can also be useful to say that there are new HIV testing guidelines which recommend this as part of good medical practice as a way of reassuring the patient that you are not making judgements.



# SECTION 3

## How to diagnose HIV in non-HIV specialist secondary care settings

### IN THIS SECTION

<b>3.1 Acute and emergency medicine</b>	<b>26</b>
<b>3.2 Respiratory medicine</b>	<b>29</b>
<b>3.3 Neurology and psychiatry</b>	<b>33</b>
<b>3.4 Dermatology</b>	<b>35</b>
<b>3.5 Gastroenterology and hepatology</b>	<b>37</b>
<b>3.6 Oncology</b>	<b>39</b>
<b>3.7 Obstetrics and gynaecology</b>	<b>40</b>
<b>3.8 Haematology</b>	<b>41</b>
<b>3.9 Ophthalmology</b>	<b>42</b>
<b>3.10 Ear, nose and throat</b>	<b>43</b>
<b>3.11 Other presentations</b>	<b>44</b>
<b>3.12 Paediatrics</b>	<b>46</b>



# How to diagnose HIV in non-HIV specialist secondary care settings

The *UK National Guidelines for HIV Testing 2008* contain a table of clinical indicator diseases for adult HIV infection, and a separate table for paediatric HIV infection. The table is divided by medical specialty area and the nine specialties listed in the table are those in which undiagnosed HIV infection is most likely to be encountered. It lists AIDS-defining conditions as well as other conditions in which HIV should enter the differential diagnosis and therefore prompt the offer of an HIV test. The table is reproduced at the end of this booklet.

This section of the booklet provides a basic overview of the common presentations suggestive of HIV infection that the generalist or non-HIV specialist clinician in secondary care might encounter. It is divided by specialty, following those in the guidelines, and provides further information about how these conditions present in the HIV-infected patient. A section for acute and emergency medicine gives information on presentations which are suggestive of HIV infection and advice on testing, and a separate section on paediatrics provides some background information on HIV in children.

Inevitably, information on some conditions provided in particular specialty-specific sections will also be useful to other specialists or to generalists. Some cross-referencing is offered but the most comprehensive information will be obtained by looking through the whole of Section 3.

## 3.1 Acute and emergency medicine

Offering HIV testing in the emergency department (ED) may be difficult because of the lack of private space for confidential discussion, the busy setting and difficulty in following up patients. However, individuals with undiagnosed HIV may attend emergency services for completely unrelated medical or social reasons, or may have signs or symptoms suggestive of HIV infection. Therefore, when warranted as part of the differential diagnosis, HIV testing should be considered.

If the ED is able to deal with the patient's presenting condition and

**Acute HIV-related conditions that may present in the emergency department**

- Community acquired bacterial pneumonia. People with HIV, regardless of their level of immunosuppression, are more at risk of bacterial pneumonia. They have similar signs and symptoms to the non-HIV-infected population, eg fever, cough, dyspnoea, increased respiratory rate and sputum production.
- TB presents with malaise, weight loss, night sweats, fever, cough, sputum production (may be blood-stained), and lymphadenopathy.
- Pneumocystis pneumonia (PCP) presents with exertional dyspnoea, fever, dry cough, normal auscultation. X-ray typically shows perihilar shadowing (ground glass haze), but may be normal.
- Cryptococcal meningitis. This presents with headache, with or without classical signs of meningism. Occasionally rapid progression occurs, and the patient may present in coma.
- Cerebral toxoplasmosis. This may present with headache, fever, lethargy and confusion, progressing to fits and coma.

discharge them, and HIV is suspected, referral for HIV testing in a more appropriate setting such as a GUM clinic, infectious disease unit or primary care should be considered.

Every ED should know who is on call for HIV-infected patients locally, and those teams can offer advice about the need for urgent testing. Some EDs may be able to offer rapid testing, but if the ED is unable to perform the test and the hospital has a sexual health clinic or infectious disease unit the health adviser or specialist nurse can visit them to arrange the test in the ED and then follow up the result.

If the patient requires admission and HIV is suspected, documenting the need for HIV testing for the acute team to consider is recommended. The on-call medical team can also access emergency testing if clinically indicated via their local virology department and these results should be available within 24 hours.

Another important reason why EDs may have to test someone for HIV is if they present for post-exposure prophylaxis following sexual exposure (PEPSE). The BASHH guideline for the use of PEPSE stipulates that it should be commenced within 72 hours of exposure and, for optimal efficiency, within 24 hours. EDs are therefore expected to provide PEPSE when GUM/HIV services are closed. The guideline also states that it is mandatory to test individuals for whom PEPSE is provided, using a test with rapid result, prior to or shortly after commencing therapy<sup>20</sup>.

**HIV-related presentations**

Non-specific generalised flu-like symptoms can be associated with HIV either during primary HIV infection or with advanced symptomatic HIV.



## case study

### Presentation is not HIV-related

Mr A, a 28-year-old man from Zimbabwe, presented to the ED on a busy Saturday evening with acute back pain. He had felt his back 'give' whilst lifting a heavy sofa. On examination he was diagnosed with mild musculo-skeletal pain and was prescribed ibuprofen. The doctor then noticed some small raised purple lesions on his face, which the patient said had been present for several months. On further questioning, the patient said that he had been feeling very run down over the past six months, and had lost about 10kg in weight. He had put this down to stress, as he

was waiting for an asylum decision. He had also been worrying about his family in Zimbabwe, where his wife had recently been diagnosed with TB. The doctor then examined him more carefully. He had oral thrush and cervical lymphadenopathy.

### Learning points

- HIV should be considered in people from areas of high HIV prevalence, regardless of their presentation.
- The presence of conditions that are possibly HIV-related can be used to initiate discussions about HIV testing.

see page 44 in section 3.11 for signs of primary HIV infection

They can also be due to a related opportunistic infection or a tumour. Consider offering an HIV test for people who present at the ED with symptoms such as:

- fever
- weight loss
- night sweats
- skin problems (especially shingles)
- oral candida
- lymphadenopathy.

### 3.2 Respiratory medicine

From the early stage of HIV infection, patients are vulnerable to pathogens of the respiratory tract.

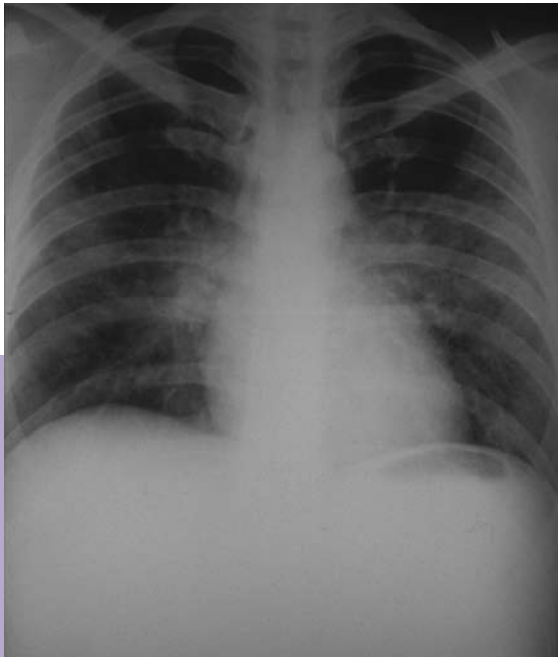
#### HIV-related presentations

##### **Pneumocystis pneumonia (PCP)**

With CD4 counts below 200 cells/mm<sup>3</sup>, pneumonia due to *Pneumocystis jirovecii* (previously known as *Pneumocystis carinii* and still commonly abbreviated to PCP) is common. It is a life-threatening infection and has a significant mortality rate. Symptoms are insidious in onset. PCP may be the first HIV-related clinical problem the patient develops and the earlier the infection is identified and treated the lower the risk of death.

#### Symptoms

- persistent dry cough
- increasing shortness of breath or decreased exercise tolerance: 'I first noticed it when I ran for a bus, but now I feel short of breath just sitting'
- difficulty in taking a full breath
- fever
- diarrhoea.



DR GARY BROOK

#### Assessment

The chest is often clear on auscultation although an increased respiratory rate is present. Fine crackles may be heard. Patients with PCP characteristically desaturate on exercise. PCP can be confused with asthma, commoner atypical chest infections and even anxiety.

Pneumocystis pneumonia in HIV

### Mycobacterial infections

**Mycobacterium tuberculosis.** TB is an important and common disease in HIV-infected patients, especially those from countries which have a high TB prevalence. Atypical mycobacterial disease (*Mycobacterium avium-intracellulare*) is less common, and is associated with late stage HIV infection.

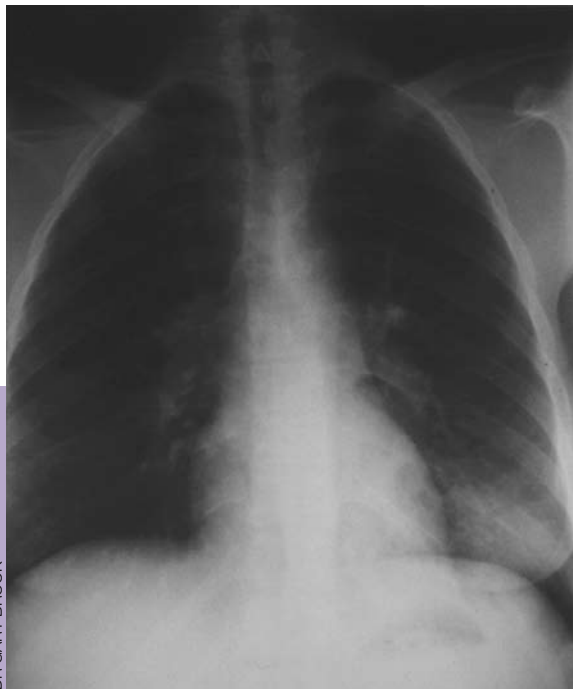
In early HIV infection, TB typically presents in a pattern characteristic of TB in the non-HIV-infected, with upper lung zone infiltrates, often with cavities. Cavities are a less common presentation of TB in the patient with a low CD4 cell count. These patients are more likely to present with either diffuse disease that may be miliary or with predominantly middle and lower lung zone infiltrates that can be mistaken for a bacterial pneumonia.

### Symptoms

The patient may have a cough, fever, sweats, shortness of breath, weight loss and haemoptysis.

**Extrapulmonary tuberculosis.** The prevalence of extrapulmonary tuberculosis is increased in HIV-infected patients. Low CD4 counts are associated with an increased frequency of extrapulmonary tuberculosis and atypical chest radiographic findings, reflecting an inability of the impaired immune response to contain infection. Patients with

extrapulmonary tuberculosis present with signs and symptoms specific to the involved site, such as lymphadenopathy, headache, meningism, pyuria, abscess formation, back pain and abdominal pain. These findings in HIV-infected patients can present a diagnostic challenge. Whenever possible, diagnostic specimens should be examined for acid-fast bacilli (AFB) and cultured for mycobacteria<sup>25</sup>.



Tuberculosis in HIV – left lower lobe

## Respiratory problems related to HIV

### Infections

#### Bacterial

- *Streptococcus pneumoniae*
- *Haemophilus influenzae*
- Gram-negative bacilli (*Pseudomonas aeruginosa*, *Klebsiella pneumoniae*)
- *Staphylococcus aureus*

#### Mycobacterial

- *Mycobacterium tuberculosis*
- *Mycobacterium avium-intracellulare* (MAI), *Mycobacterium avium complex* (MAC)

#### Fungal

- *Pneumocystis jirovecii*
- *Cryptococcus neoformans*
- *Aspergillus* species
- *Candida* species

#### Viral

- Cytomegalovirus (CMV)
- Herpes simplex virus (HSV)

#### Parasitic

- *Toxoplasma gondii*
- *Strongyloides stercoralis*

#### Neoplasms

- Kaposi's sarcoma (KS)
- Non-Hodgkin's lymphoma (NHL)

### Other respiratory illnesses

#### Upper respiratory

- Upper respiratory tract infection (URTI)
- Sinusitis
- Pharyngitis

#### Lower respiratory

- Lymphocytic interstitial pneumonitis (LIP)
- Non-specific interstitial pneumonitis (NIP)
- Acute bronchitis

***Mycobacterium avium-intracellulare*** (MAI) – also called ***Mycobacterium avium complex*** (MAC). This may cause systemic symptoms including fever and diarrhoea. Chest symptoms may or may not be present. Abnormal liver function and anaemia may be found. *Mycobacterium avium-intracellulare* is very unlikely in a patient without several clinical pointers to HIV disease because it occurs at very low CD4 counts.

### Assessment

Usual assessment for TB (chest X-ray, sputum analysis). The NICE guidelines for managing TB<sup>26</sup> recommend that all patients with TB are risk assessed for HIV.

### 'Ordinary' chest infections

The commonest organisms causing lung infections in the general population, eg *Streptococcus pneumoniae* and *Haemophilus influenzae*, are also a major cause of chest infections in immunocompromised patients. They present with symptoms similar to those seen in HIV-negative

## case study

### Chest infection

Mr B, aged 36, was referred to the local ED by his GP. He gave a 10-day history of increasing dyspnoea and non-productive cough, unresponsive to oral amoxicillin, on the background of several weeks of fever with sweats and weight loss of 5kg. On examination he was cyanosed, and there were fine crackles in both lung bases. A CXR showed bilateral diffuse infiltrates, O<sub>2</sub> saturation 90 per cent on room air PaO<sub>2</sub> (on air) = 7.9 kPa, WBC = 12.3 (90 per cent = neutrophils). The initial diagnosis was severe community-acquired pneumonia and the patient was admitted to hospital by the general medical team, given supplemental oxygen by face mask, and parenteral cefuroxime and clarithromycin.

On the 'post take' ward round the next morning he was re-assessed. He remained hypoxaemic and re-examination revealed oral hairy leukoplakia and marked oral candidiasis. Underlying immune suppression was suspected. Treatment was changed to IV high dose co-trimoxazole with adjuvant glucocorticoids. At bronchoscopy a few days later cysts of *Pneumocystis jirovecii* were

identified in lavage fluid – confirming a diagnosis of Pneumocystis pneumonia (PCP).

After discussion with the medical team the patient agreed to an HIV test. He reported that he had had receptive unprotected anal intercourse with several male partners following the breakdown of a long-term

relationship some six years previously. The HIV test was positive and a CD4 count was 120 cells/mm<sup>3</sup>. The patient was referred to the HIV specialist team and, following completion of treatment for PCP, began combination antiretroviral therapy. On the advice of the HIV team he gave permission for all results to be shared with his GP.

Make sure that the discharge summary sent to the GP includes reason for admission, the HIV diagnosis, medication details and arrangements for follow-up.

### Learning points

- Consider PCP in patients with recent onset dyspnoea or where atypical or severe respiratory infection is possible.
- People diagnosed with HIV-related problems should be referred urgently for specialist evaluation, preferably within 48 hours.
- Make sure that the discharge summary sent to the GP includes reason for admission, the HIV diagnosis, medication details and arrangements for follow-up.

patients but may be difficult to distinguish from other OIs on X-rays, in particular *H. influenzae* which can appear similar to PCP.

### Aspergillosis

Exposure to *Aspergillus* is universal, but aspergillosis is rare without significant immunodeficiency and is only seen in patients with prolonged severe immunosuppression.

### 3.3 Neurology and psychiatry

#### HIV-related presentations

Neurological complications are common in those infected with HIV.

Some neurological manifestations result from a direct encephalitic effect of HIV and others from local neoplastic lesions and infectious lesions.

Focal lesions are most commonly due to *Toxoplasma gondii*, cytomegalovirus, herpes simplex virus and lymphomas. Meningitis is most commonly caused by *Cryptococcus neoformans* and more rarely due to tuberculosis or bacterial infections.

#### Neuropathies

Peripheral neuropathies are common in HIV-infected patients and may be a result of:

- HIV
- opportunistic infection
- a complication of medication (mainly associated with didanosine and stavudine, and less commonly with lamivudine)
- nutritional deficiency (eg B12 or folate deficiency).

#### HIV-related conditions that may present in a neurology clinic

- Toxoplasmosis presents with focal neurology evolving over a few days.
- Cryptococcal meningitis presents with headaches. Meningeal symptoms may be absent. Occasionally the patient may present in coma.
- Cytomegalovirus (CMV) encephalitis presents with confusion, lethargy, cranial nerve palsies and nystagmus; it occurs with advanced immunosuppression.
- HIV encephalopathy presents with cognitive and motor impairment.
- Progressive multifocal leucoencephalopathy (PML) presents with weakness, headaches, speech impairment, altered vision and weight loss. Caused by a human polyomavirus (JC virus).

- Primary cerebral lymphoma (also known as primary CNS lymphoma (PCNSL)) is a cause of cerebral mass lesions in patients with advanced HIV disease. The most common signs and symptoms are confusion, lethargy, and personality changes or focal deficits, eg hemiparesis, hemisensory loss, ataxia, and aphasia.

#### Other neurological conditions that can be associated with HIV

- Aseptic meningitis/encephalitis
- Cerebral abscess
- Space-occupying lesion of unknown cause
- Guillain-Barré Syndrome
- Transverse myelitis
- Peripheral neuropathy
- Dementia
- Leucoencephalopathy



Patients may present with:

- Guillain-Barré syndrome
- Transverse myelitis.

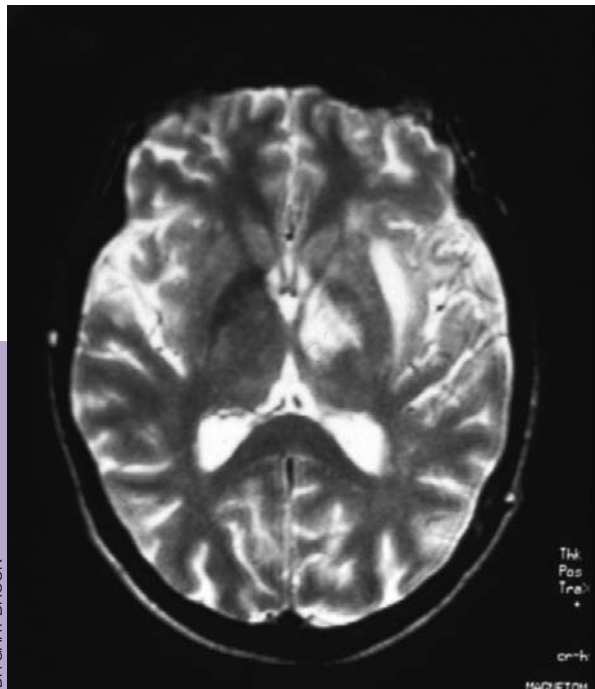
### **HIV encephalopathy**

HIV encephalopathy, also known as HIV or AIDS-related dementia, is one of the most common and clinically important CNS complications of late HIV infection. While its pathogenesis remains unclear it is generally thought to be caused by HIV itself, rather than another opportunistic infection.

### **Neurosyphilis**

In the United Kingdom, there has been a recent resurgence of syphilis. Gay men have been disproportionately affected and around half of these men were HIV-positive. Therefore, there should be a high index of suspicion of HIV after any presentation of syphilis.

Symptomatic early neurosyphilis is a rare manifestation that usually occurs within the first 12 months of infection. Symptoms include meningitis, cranial and optic nerve function abnormalities, uveitis and stroke.



MRI scan of progressive multifocal leucoencephalopathy

3.4 Dermatology

**HIV-related conditions that may present in a dermatology clinic**

**Fungal/yeast**

- Candida (oral or oesophageal)
- Tinea infections (corporis, cruris, pedis, interdigitale etc)
- Pityriasis versicolor
- Seborrhoeic dermatitis (especially when severe or recalcitrant)
- Pityrosporum folliculitis

**Viral**

- Herpes zoster
- Herpes simplex
- Viral wart infections
- Molluscum contagiosum

**Bacterial**

- *Staphylococcus aureus*-impetigo, chronic folliculitis

**Mycobacterial**

- *M tuberculosis*

**Infestations**

- Scabies (especially Norwegian scabies)

**Other**

- Psoriasis
- Kaposi's sarcoma
- Acne

All of these skin conditions can occur without HIV, but consider HIV particularly if they are recalcitrant, recurrent or atypical.

**HIV-related presentations**

Skin conditions occur in more than 90 per cent of people with HIV during the course of their infection. Some people have an exacerbation of a pre-existing condition, such as psoriasis. This often occurs when the patient becomes increasingly immunocompromised. Others may have new skin problems, most of which are commonly found in the general population, although some, such as Kaposi's sarcoma, are strongly suggestive of associated HIV infection.

Seborrhoeic dermatitis



DR MA ANSARY/SCIENCE PHOTO LIBRARY

Kaposi's sarcoma



DR GARY BROOK

## case study

### Common skin problems

Mr G was a 19-year-old student. He had returned two weeks previously from his gap year in Malawi, where he had taught secondary school English. He had had mild psoriasis since age 10, which was well-controlled whilst he was in Africa. Immediately after returning his skin had flared up worse than ever before. He was single, a non-smoker, and drank 20 units of alcohol a week. He was referred by his GP to the dermatology clinic. The registrar treated him for psoriasis with topical corticosteroids and vitamin D analogues and arranged review in two weeks.

On review his rash was worse and he was pyrexial with enlarged cervical glands. Another doctor examined him and recognised that the rash was morbilliform and not typical of a psoriasis exacerbation. The doctor asked Mr G about his sexual history. He said that he had had a girlfriend in Malawi, and that they did not always use condoms. He had never had any sexually transmitted infections. The doctor

Mr G was distraught when he got the results and initially stated that he did not want anyone to be told about his result, including his GP.

took blood for appropriate tests which confirmed primary HIV infection. Mr G was distraught when he got the results and initially stated that he did not want anyone to be told about his result, including his GP. He was

referred to the HIV specialist team and, after further discussion of the issues with the health adviser, he agreed that it was in his best interests to inform his GP.

### Learning points

- HIV infection can often exacerbate common skin conditions.
- People diagnosed with HIV in any setting should be referred for specialist evaluation within a maximum of two weeks, preferably within 48 hours (national *Standards for HIV Clinical Care*).
- Although sometimes people with newly-diagnosed HIV are initially reluctant to share their HIV result with their GP, it is almost always in the patient's best interest to establish normal communication with the GP.

### 3.5 Gastroenterology and hepatology

#### HIV-related presentations

##### Diarrhoea

Acute or chronic diarrhoea can be a feature of HIV at any stage of the infection. Diarrhoea is most commonly due to an infection and much more rarely due to HIV enteropathy or malignancies such as Kaposi's sarcoma, lymphoma or bowel cancer. Symptoms of colitis or small-bowel watery diarrhoea are common, and often very distressing.

##### Oesophageal candidiasis

This is seen in patients with a low CD4 count, high viral load and neutropenia. It presents with dysphagia, odynophagia, retrosternal pain, nausea and vomiting. Oropharyngeal candidiasis is nearly always present.

##### Cholangitis

Patients with HIV can also present with cholangitis secondary to opportunistic infections such as CMV, cryptosporidiosis or microsporidial infection (usually in those who are severely immunocompromised).

##### Hepatitis

Co-infection of HIV with hepatitis B and/or C is not unusual and the infections share the same risk factors.

#### Causes of diarrhoea in people with HIV

##### Bacterial

- *Campylobacter* and *Salmonella* species are more likely to produce bacteraemia in people with HIV. Consider HIV testing in anyone with salmonella bacteraemia
- Enteroaggregative *Escherichia coli* (EAggEC) and other *E coli*
- *Clostridium difficile*

##### Protozoal

- *Cryptosporidium* species (AIDS-defining when persistent)
- *Giardia lamblia*
- *Isospora belli*
- *Entamoeba histolytica*
- *Microsporidium* species (only in severely immunocompromised)

##### Mycobacterial

- *Mycobacterium avium-intracellulare* (MAI) (only in severely immunocompromised)

##### Viral

- Adenovirus
- CMV (only in severely immunocompromised)

##### Non-infectious

- Kaposi's sarcoma
- Lymphoma
- Cytopathic effects of HIV – chronic diarrhoea of unknown cause, weight loss of unknown cause

## case study

### Hepatitis C co-infection

A 35-year-old man, Mr C, was referred by his GP to the gastroenterology clinic. He had been complaining of tiredness and general malaise for several months and the only abnormality the GP had found was mildly elevated liver enzymes. He acknowledged having used intravenous drugs a few times as a teenager and was tested for hepatitis C and HIV infection. Hepatitis C antibody was detectable, his liver function tests were mildly abnormal and his subsequent liver biopsy revealed early fibrosis. He was referred for treatment of his hepatitis C with interferon and ribavirin.

His HIV test was also positive with a CD4 count of 550 cells/mm<sup>3</sup> and an HIV viral load of 2,000 copies/ml. He was referred to the

specialist HIV unit to be assessed for ART.

He was also offered advice about reducing his alcohol intake and reducing the risk of transmitting HIV and hepatitis C to future partners. Patients who have hepatitis C and HIV are more likely to transmit hepatitis C sexually.

### Learning points

- Improved survival of patients with HIV means that hepatitis C co-infection should be actively sought and treated to prevent progression to cirrhosis and hepatocellular carcinoma.
- Co-infected patients should be referred to the HIV specialist team as soon as possible for assessment for ART regardless of their CD4 count and viral load.

Co-infected patients have an increased risk of progressing to cirrhosis and developing hepatocellular carcinoma.

All patients with hepatitis B or C should be tested for HIV, as knowing about the dual diagnosis significantly alters the way both conditions are managed.

### 3.6 Oncology

#### HIV-related presentations

Some malignancies are clearly associated with HIV infection and their diagnosis classifies an HIV-infected patient as having developed AIDS. The three AIDS-defining cancers are:

- Kaposi's sarcoma
- non-Hodgkin's lymphoma
- cervical cancer.

However, there is an increasing number of other cancers which are more common in those with HIV than in the general population<sup>27</sup>. The cancers observed to occur more frequently in HIV-infected patients are:

- anal cancer and anal intraepithelial neoplasia (AIN)
- vaginal intraepithelial neoplasia (VIN)
- Hodgkin's lymphoma
- liver cancer
- lung cancer
- melanoma
- head and neck cancer
- oropharyngeal cancer
- colorectal cancer
- leukaemia
- renal cancer
- seminoma
- Castleman's disease.

As both Hodgkin's and non-Hodgkin's lymphomas are associated with HIV infection, the *UK National Guidelines for HIV Testing 2008* recommend that all individuals with lymphoma should be tested for HIV.

Primary CNS lymphoma is more common in HIV-infected patients than in the general population, although it is a feature of late-stage disease.

In children with HIV, leiomyosarcoma and leiomyoma are also seen more commonly.



Cutaneous lymphoma

### 3.7 Obstetrics and gynaecology

Since 2000 there has been a universal antenatal screening policy for HIV. All pregnant women in the UK are routinely recommended and offered an HIV test during pregnancy<sup>28</sup>.

Uptake of antenatal HIV testing is now over 90 per cent and more than 80 per cent of HIV infections in pregnant women are diagnosed prior to delivery.

The *UK National Guidelines for HIV Testing 2008* recommend universal HIV testing for all women attending termination of pregnancy services. This is based on evidence from unlinked anonymous seroprevalence surveys conducted in inner London termination clinics that there is a consistently higher prevalence of HIV infection in women terminating their pregnancies compared with those giving birth.

#### HIV-related presentations

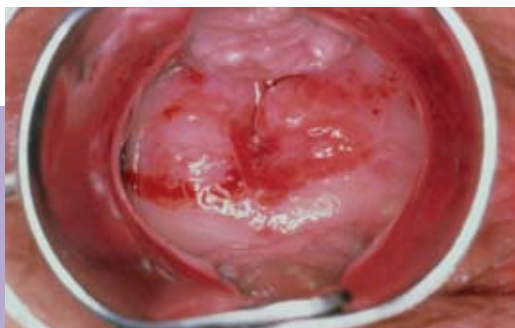
Women with HIV, especially those with a low CD4 count, are more at risk from human papilloma virus (HPV)-related disease, including cervical intraepithelial neoplasia (CIN), cervical cancer, vaginal intraepithelial neoplasia (VIN) and genital warts. HIV should be considered in women with cervical cancer.

#### Incidental findings

HIV testing should also be considered in women with vaginal candidiasis, genital herpes and pelvic inflammatory disease (PID), particularly if the presentations are chronic or florid or if they have other HIV risk factors. Smear abnormalities suggestive of HPV infection should also prompt consideration of an HIV test.

The *UK National Guidelines for HIV Testing 2008* recommend that any diagnosis of a sexually transmitted infection should prompt the offer of an HIV test.

Some fertility clinics are now offering HIV testing as routine to patients.



Cervical cancer



Florid genital warts

### 3.8 Haematology

#### HIV-related presentations

Significant haematological abnormalities are common in those with HIV. Impaired haematopoiesis, immune-mediated cytopaenias (anaemia, thrombocytopenia, neutropenia and lymphopaenia) and altered coagulation mechanisms have all been described. These abnormalities may occur as a result of HIV infection itself, as sequelae of HIV-related infections or malignancies or as a consequence of drugs used to treat HIV infection and associated conditions. Changes on a routine blood count may therefore suggest HIV infection and it should be routinely considered in individuals with unexplained thrombocytopenia or neutropenia.

**Anaemia** is a common finding in patients with HIV, particularly in individuals with more advanced disease. A common infectious cause is *Mycobacterium avium-intracellulare* (MAI) and other causes are rarer, eg B19 parvovirus. Gastrointestinal (GI) bleeding can also be the cause of anaemia. In addition to the usual causes of gastrointestinal blood loss, HIV-related infections such as cytomegalovirus colitis and malignancies such as Kaposi's sarcoma and non-Hodgkin's lymphoma may produce clinically significant GI bleeding in people with HIV.

**Thrombocytopenia** is frequently associated with HIV infection. Possible aetiologies include immune-mediated destruction, thrombotic thrombocytopenic purpura, impaired haematopoiesis, and toxic effects of medications. Often, however, thrombocytopenia is an isolated haematologic abnormality associated with normal or increased megakaryocytes in the bone marrow and elevated levels of platelet-associated immunoglobulin. These patients have the clinical syndrome commonly referred to as immune thrombocytopenic purpura (ITP).

**Neutropenia** and **lymphopaenia** are common in those with HIV infection. Low lymphocyte counts often reflect a low CD4 count and this should prompt HIV testing. There is a high incidence of neutropenia and lymphopaenia in those with more profound immunodeficiency.



## 3.9 Ophthalmology

**HIV-related conditions that may present in an ophthalmology clinic****Protozoal**

- *Toxoplasma gondii*

**Viral**

- Herpes zoster ophthalmicus
- Herpes simplex keratitis
- CMV retinitis
- Herpes simplex virus
- Herpes zoster virus retinitis

**Fungal**

- Microsporidial keratoconjunctivitis

**Other**

- Kaposi's sarcoma
- Lymphoma

**HIV**

- Can cause retinal haemorrhages and cotton wool spots, and rarely optic neuropathy
- Retinal arterial occlusion

**HIV-related presentations**

Unexplained or atypical retinopathies or uveitis may indicate underlying HIV infection. HIV itself commonly causes retinal haemorrhage and cotton wool spots and rarely optic neuropathy. Kaposi's sarcoma may spread to involve the conjunctivae, eyelids and orbit in patients who are severely immunocompromised.

Vision can also be compromised by infections with cytomegalovirus (CMV), herpes simplex virus, syphilis, herpes zoster virus and *Toxoplasma gondii*.

CMV retinitis can cause blindness if untreated. It is usually seen in severely immunocompromised patients with a CD4 count of less than 100 cells/mm<sup>3</sup>. CMV retinitis may be the first presentation for people with HIV.



HIV retinitis



CMV retinitis

### 3.10 Ear, nose and throat

#### HIV-related presentations

Signs of HIV infection are commonly found in the mouth:

- oral candidiasis
- aphthous ulceration
- recurrent severe herpes simplex infection
- oral hairy leukoplakia is pathognomonic of immunosuppression
- gingivitis, especially if necrotising or ulcerative
- Kaposi's sarcoma
- dental abscess
- chronic parotitis. In some studies 40 per cent of children with HIV have parotid enlargement, with a median time from birth to development of 4.6 years. Parotitis in children is associated with a slower rate of disease progression.

HIV should also be considered in patients with persistent cervical lymphadenopathy, which may be due to HIV itself or secondary to infections (especially TB) and tumours (especially lymphoma).

Infection or inflammation of the sinuses is a common problem among people with HIV and its severity increases in people with lower CD4 cell counts.



Oral hairy leukoplakia

## 3.11 Other presentations where HIV testing should be routinely offered

The *UK National Guidelines for HIV Testing 2008* list several other conditions which should prompt consideration of HIV infection if they are present. Oral candidiasis and oral hairy leukoplakia are covered in Section 3.10 (Ear, nose and throat).

### Primary HIV infection

Although the opportunity to diagnose primary HIV infection is limited by the short duration of the symptoms and their non-specific nature, making the diagnosis correctly is valuable because:

- the next opportunity for diagnosis may be at a late stage of disease progression, and so the prognosis for the patient is likely to be worse
- early detection may protect other people from becoming infected as at the time of seroconversion the patient may be very infectious.

#### If you suspect primary HIV infection

- A useful rule of thumb is that if you are considering glandular fever (mononucleosis) then you should also consider primary HIV infection.
- Take a history and conduct an examination to look for evidence of primary HIV infection.
- Symptoms can be non-specific, but include fever, sore throat, malaise or lethargy, arthralgia and myalgia, headache and cervical lymphadenopathy.
- Symptoms and signs that are more specific to primary HIV infection include rash affecting the trunk, and orogenital or perianal ulceration. Diarrhoeal illness or aseptic meningitis may occur.
- The CD4 count may drop acutely at this stage of HIV infection, and so acute conditions associated with immunosuppression may occur.
- If you remain concerned, raise the subject with the patient, eg 'Illnesses like this are usually caused by viruses – the glandular fever or flu virus. Some quite rare viruses can also be a cause, such as HIV and we routinely check for HIV in cases like this'.

### Pyrexia of unknown origin

Pyrexia of unknown origin (PUO) covers a broad range of possible diagnoses.

PUO in inpatients who have not been diagnosed with HIV should therefore prompt consideration of HIV infection and inclusion of HIV testing in their investigations (see above). PUO in the context of a tropical infectious disease should also prompt consideration of HIV in patients who have been abroad recently and who present with symptoms.

In patients with advanced HIV infection prolonged febrile episodes are frequent. The causes are mainly the result of opportunistic infections or malignancies and rarely are due to HIV itself.

### Any sexually transmitted infection

The British Association for Sexual Health and HIV recommends that all patients presenting to GUM settings with symptoms of a

## case study

### Primary HIV infection

Miss J was a 30-year-old university lecturer who presented at the ED with a five-day history of fever, headache, sore throat and a sore mouth. She said she was worried that she might have malaria, as she had returned from a safari holiday in Namibia about 10 days previously, although she had taken antimalarials as prescribed whilst away. On examination, Miss J was pyrexial with mouth ulcers. The malaria slide and malarial antigen tests were negative, her ESR was raised and

she had slight neutropenia. Miss J agreed to have an HIV test. The p24 antigen was positive and the HIV antibody test negative, confirming primary HIV infection. She then stated that she had had unprotected sex with the tour guide whilst on her safari.

### Learning point

- Consider primary HIV infection in people with fever returning from overseas travel to areas of high HIV prevalence.

sexually transmitted infection (STI), or for a routine STI screen, should be tested for HIV.

The behavioural risk factors for most STIs are the same as those for HIV (unprotected vaginal or anal intercourse) and this should prompt an HIV test even in those patients who do not belong to one of the main at-risk populations.



Primary HIV Infection rash

## 3.12 Paediatrics

written by Dr Hermione Lyall, Family HIV Centre, St Mary's Hospital, London

There are currently around 1,200 HIV-infected children living in the UK and Ireland. All infants born to mothers with HIV and all children diagnosed with HIV are reported to the national cohort (for more details see [www.nshpc.ucl.ac.uk](http://www.nshpc.ucl.ac.uk) and [www.chipscohort.ac.uk](http://www.chipscohort.ac.uk)). Children may be diagnosed with HIV because they present with symptoms or because they are tested after their parents or siblings are found to be HIV-infected.

Infants are at particular risk of severe HIV disease and up to 20 per cent will develop an AIDS diagnosis or die within the first year of life if they do not receive appropriate treatment. Infants most often present with PCP, CMV disease, HIV encephalopathy, and/or failure to thrive.

After the first year of life older children may present with recurrent infections (eg of the ear, chest or skin) or more severe manifestations of common childhood infections (eg severe chicken pox). A common

presentation of HIV in children is with chronic painless swelling of the parotid glands (the glands in front of the ears which enlarge with mumps), as well as chronic enlargement of the cervical glands and recurrent upper respiratory infections. This is often accompanied by lymphoid interstitial pneumonitis (LIP) where there is infiltration of the lungs with nodules of inflammatory lymphocytes. This is usually asymptomatic, but has a characteristic



Paediatric shingles



Paediatric parotid swelling

appearance on chest X-ray which can be difficult to distinguish from miliary tuberculosis. Children of any age with more advanced immunodeficiency may

present with AIDS diagnoses similar to those seen in adults.

With access to treatment and adequate adherence support infants and children respond very well to ART with the prospect of long-term survival into adult life. Treatment of HIV in children in the UK is managed within the Children's HIV National Network (CHINN) and led by paediatric infectious disease specialists working alongside local teams according to where the child lives. Children with HIV should be treated according to the Paediatric European Network for the Treatment of AIDS (PENTA) guidelines<sup>29</sup> which are endorsed by the Children's HIV Association of the UK and Ireland (CHIVA).

### **Consider HIV in children if a parent is diagnosed**

If an adult is diagnosed with HIV then they must always be asked if they have children.

Children and young people may be infected with HIV and never have presented with symptoms even up to 20 years of age. Therefore, whatever a child or young person's age, if a family member has been diagnosed with HIV then they should always be recommended a test.

## case study

### Late diagnosis in a child

Mrs O had lived in the UK for 10 years, and was originally from Uganda. She brought her 14-year-old niece, B, to the GP's surgery as she was worried about some painful spots on her leg. The GP diagnosed shingles affecting L2-4 dermatomes and the lesions resolved after treatment with acyclovir.

On review, Mrs O informed the GP that B had arrived in the UK six months previously to live with her as her own mother had recently died of tuberculosis. Her father had died of cancer four years previously, and her baby

brother had died of pneumonia seven years ago at three months of age.

The GP recommended that with B's recent shingles and her family history, she should have an HIV test. She performed the test herself and when the result came back it was positive.

### Learning points

- Some children with HIV only present with symptoms in the second decade of life.
- Always take a family history; this may identify risk factors for HIV in a child with or without significant symptoms.

## case study

### HIV infection during pregnancy

Ms S had a negative HIV test in pregnancy when she was booked at 12 weeks. By the time her baby, A, was 14 weeks old he had been treated twice by the GP for oral thrush which had persisted. Two days ago A was admitted to the Paediatric Intensive Care Unit (PICU) with severe pneumonia, now very ill and on a ventilator. The PICU doctor informed Ms S that A had a very severe kind of pneumonia called PCP, which usually only occurs in infants with immune deficiency. The doctor advised that his immune system needed to be tested and that this would involve an HIV test.

Ms S explained that she had had a negative HIV test in pregnancy so she did not think that A could have HIV. The doctor explained that if a mother becomes infected with HIV during pregnancy or whilst breastfeeding then she has a high chance of passing it to her baby, as during primary HIV

infection there is a very high level of the virus in her blood which could infect the baby

during birth, and in the breast milk which may pass to the baby during feeding.

Ms S then told the doctor that A's father was from Zimbabwe and that he had returned from a three-month visit there when she was seven months pregnant. She agreed

to the HIV test and the result was positive.

Even though a mother has had a negative HIV test at booking this does not mean her infant cannot have HIV

### Learning points

- Even though a mother has had a negative HIV test at booking this does not mean her infant cannot have HIV.
- Pregnant and lactating women should be advised to have protected sex to prevent transmission of sexually transmitted infections which may cause disease in mother and foetus/baby (eg HIV, syphilis, gonorrhoea, chlamydia).

# SECTION 4

## Pre-test discussion

### IN THIS SECTION

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**Written consent** 51

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**Patients who decline a test** 51

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# Pre-test discussion

see page 22  
for how to offer an  
HIV test

The term 'pre-test discussion' is considered to be more appropriate than 'pre-test counselling'<sup>17,8,9,10</sup> which was previously used and implied the need for in-depth counselling by a specially-trained healthcare worker. For the clinician, the main reason for a pre-test discussion is to ensure the patient's informed consent to be tested for HIV. However, for the patient it is an opportunity to consider the possible outcomes and their consequences in the broader context of their own lives. The time a discussion may take is variable. With a well-informed, reasonably low-risk person the discussion may take just a minute or two, but with a person from a marginalised group with a high risk of HIV infection there are many factors which can impact upon their decision to take an HIV test. These are discussed more fully in section 6.

It is helpful to give the patient printed information on HIV testing in your service which you can go through with them. This will help you ensure you have covered all the necessary areas before proceeding with the test. The following is a breakdown of the essential areas that need to be covered in a pre-test discussion.

## Discuss the benefits of performing an HIV test

As when proposing any clinical investigation it is important to inform the patient of the rationale for testing in a manner which is appropriate to their situation.

There are various reasons why a patient may be apprehensive about taking an HIV test so you should be clear with them about the medical advantage of knowing their HIV status. The advantage of early detection and referral for treatment, referral for support services and prevention of transmission to sexual partners should be emphasised.

Some patients, particularly those who are asymptomatic, may believe they are better off not knowing. Others may fear stigma, discrimination, loss of employment, or the detrimental impact of a positive test result on immigration procedures, so reassurance about confidentiality is important.

Such concerns should be listened to, addressed and balanced against the significant advantages of knowing one's status if positive.

Some patients may find the use of the term 'positive' to be confusing and it has been known for patients to equate 'positive' with 'good news', and to assume therefore that they do not have HIV. This should be clarified, particularly for those for whom English is not their first language.

## Make arrangements for giving the test result

Ideally the result is best given in person by the individual who performed the test, and in an environment where the discussion cannot be overheard. Give the patient the details of the appointment and who they

see page 60  
for patients'  
barriers to HIV  
testing

will be seeing to get the result. Record contact details, check the patient's preferred method of contact, and check for any possible problems with leaving messages or talking. This is particularly important if the patient fails to attend for a result that turned out to be positive.

Once informed consent is established, record in the notes that pre-test discussion has taken place and consent obtained. Record in the notes who is going to give the results and date of the appointment. Explain that a positive test result will need to be recorded in a patient's medical records so that their healthcare remains safe and appropriate. Also record if the patient has agreed for the results to be sent to any other healthcare professional involved in their care, eg their GP.

### **Written consent**

Written consent is not required for an HIV test. The General Medical Council's guidance on consent, *Consent: patients and doctors making decisions together* contains the following statement which appears to imply that written consent would be needed:

'49. You should also get written consent from a patient if:  
...b. there may be significant consequences for the patient's employment, or social or personal life'.

The GMC advises in the introduction to the document that '...'you should' is also used where the duty or principle will not apply in all situations or circumstances<sup>30</sup>' in discussion with the authors of the *UK National Guidelines for HIV Testing 2008* has agreed that this provision is adequate to exempt HIV testing from written consent requirements.

### **Patients who decline a test**

Sometimes a patient will refuse a test and the reasons for this should be explored as they may have incorrect information about HIV transmission or the consequences of testing, such as concerns about confidentiality or insurance.

For patients who are at high risk of HIV infection but decline testing in your setting, it may be better to recommend referral to a specialist service (GUM clinic, infectious disease clinic or voluntary sector organisation) where they can discuss their concerns more fully and where additional support is available.

Where patients do not have English as a first language, it is advisable not to use family members or friends of the patient as interpreters when discussing HIV testing as this may breach confidentiality, so consider rescheduling an appointment with an interpreter from a recognised service.

It is important to bear in mind that, as with any investigation, patients have a right to refuse and are not obliged to give a reason. They should not be pressured or coerced into testing against their own judgement. If this happens, it is important to document this in the notes, along with any reasons the patient gives for declining the test.



# SECTION 5

## Post-test discussion

### IN THIS SECTION

<b>Post-test discussion for individuals who test HIV-negative</b>	<b>54</b>
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<b>Post-test discussion for individuals who test HIV-positive</b>	<b>55</b>
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<b>Non-attendance for HIV test results</b>	<b>57</b>
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<b>Providing written confirmation of results</b>	<b>58</b>
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# Post-test discussion

Giving a patient the result of an HIV test should be no more or less difficult than giving any other test result, especially when the result is negative. Giving a positive result will require your skills in breaking bad news to patients, and most clinicians will have to give test results which are life-altering and which can upset the patient at some point in their careers.

Whatever the result of the HIV test, clear procedures should be in place for giving results, as is the case with other tests. It is considered good practice to arrange with the patient how the result will be given when the test is taken and this is particularly important for outpatient and emergency care settings.

Some GUM clinics give negative HIV test results by phone or by text message to reduce the number of follow-up appointments a busy service has to make and if this is acceptable to the patient, your clinic or service may wish to consider this.

However, for certain groups of patients it is strongly recommended that any HIV test results are given in person. These are:

- ward-based patients
- those more likely to have an HIV-positive result
- those with mental health issues
- those for whom English is a second language
- young people under 16 years
- those who may be anxious or highly vulnerable.

Depending on how well you know the patient, the pre-test discussion may be the last opportunity to assess how they might react to the result, so it is important that you record in the notes of that discussion any signals the patient gave about their state of mind or level of vulnerability. This may include the need for early referral to support services within the hospital or to voluntary and community-based organisations.

## **Post-test discussion for individuals who test HIV-negative**

If you have initiated an HIV test on clinical grounds, eg in order to exclude HIV from the differential diagnosis, giving a negative result should be straightforward and it is likely that you will need only to refer to your original grounds for testing to give it.

The *UK National Guidelines for HIV Testing 2008* refer to providing advice about minimising risk or behaviour change. This recommendation is appropriate to HIV testing in primary care settings. In a small number of situations, however, the secondary care generalist may have to offer an HIV test on account of a patient's behavioural risk factors in addition to being part of the clinical investigation. These factors may then have to be

addressed when giving the test result. If you feel confident to provide such health promotion and advice, then it is good practice to do this yourself as part of the post-test discussion. This could include post-exposure prophylaxis (PEP) for those individuals at high risk of repeat exposure to HIV infection and referral to HIV prevention services including drug treatment/harm reduction programmes where appropriate. If you don't feel able to do this effectively, then refer the patient to GUM or HIV services or voluntary sector agencies.

The patient should understand the significance of the window period and be made aware that a repeat test may be needed if exposure has occurred within that time. Although the standard blood test for HIV can detect it as early as 28 days after exposure, it is currently recommended that the test is repeated if exposure has occurred within the last three months. Ensure that the patient understands that they may need a repeat test before HIV infection can be ruled out and that they should continue with safer sex practices to prevent onward transmission as, if they are infected, this is one of the most infectious stages of the disease. Once again, referral to the HIV specialist unit may be the most appropriate course of action.

Some HIV test results may be inconclusive, and are usually reported as 'reactive' or 'equivocal'. This could occur in a patient who has primary HIV infection presenting to emergency services. There are good reasons for detecting people with HIV as early as possible in the infection so such patients should be promptly referred to specialist HIV care for assessment and the management of re-testing.


### **Post-test discussion for individuals who test HIV-positive**

Although no patient welcomes a life-altering diagnosis, the situation for people with HIV in the UK is much more optimistic than it was 20 or even 10 years ago. If patients are provided with clear information about the availability and effectiveness of antiretroviral therapy, and made aware of the possibility that they can continue working, have sexual relationships, conceive safely and have children with minimal risk of passing on HIV, many of their immediate fears will be alleviated. There are many agencies that support people and families affected with HIV. A list of national organisations, with websites and telephone contacts, is given at the end of this booklet.

If the result is positive, here are some things to consider before the patient attends.

### **Preparing to give a positive result**

You will have time to seek advice if necessary because the lab is likely to phone the result through and ask for a repeat sample. If this is the first positive HIV test result you have had to give it may be possible to arrange



see page 80 for  
details of national  
support services

for someone from the HIV specialist unit such as a clinical nurse specialist or health adviser to attend the consultation to assist you. Remember:

- you already have skills in discussing difficult issues with patients
- the patient agreed to do their test on your recommendation and will be expecting you to give them the result.

## **Referral arrangements**

The national *Standards for HIV Clinical Care* (2007) recommend that any patient receiving a positive HIV test result in any setting should be referred to a specialist HIV clinic within two weeks for assessment and management, and preferably within 48 hours. If you are giving a positive HIV test result in any secondary care setting you should ensure you have details of the nearest HIV specialist service so that an appointment can be made when the patient attends for their result.

## **When the patient attends**

Give the result soon after the patient is in the room and is seated. Delaying disclosure can heighten anxiety. Some patients are expecting a positive result and may be quite calm. Some may have already come to terms with being positive, but a calm exterior can mask a sense of shock.

Tell the patient that their HIV care will be managed by the specialist team who will undertake a full assessment and be able to answer questions about prognosis, treatment options and reducing the risks of onward transmission so you will not need to be familiar with the complexities of these matters. Remember to re-emphasise that the patient is better off knowing that they have HIV than not knowing.

The *UK National Guidelines for HIV Testing 2008* also refer to providing detailed post-test discussion and partner notification. Once again, this is more likely to be relevant to HIV testing in primary care settings, but it is certainly the case that some people diagnosed in secondary care will need in-depth and ongoing counselling to help them cope following an HIV diagnosis. Referral to specialist counselling services or HIV support groups is appropriate and details of these will usually be available from GUM/HIV services.

When the consultation is coming to an end:

- give the patient the details of any referral arrangements/appointments that you have set up
- remind the patient that their future HIV care should be with the HIV specialist, whether or not you need to see them again.

It is possible that patients with HIV will be anxious about how their HIV status is to be kept in their records. It is best to raise the subject so that this issue can be addressed and the benefits outlined, as well as making clear the potential risks should the diagnosis not be clearly recorded.

### **The importance of informing and involving the GP**

Tell the patient that it is standard practice for specialists to inform a patient's GP of the results of any test or procedure performed in hospital, and that the HIV specialist team will 'let the GP know about all your test results so that he/she can help in your future care'. Some patients may initially be reluctant to have their GP made aware of their positive HIV

status, so you should highlight the advantages of sharing results with the GP. If a patient is not registered with a GP they should be encouraged to register and be given information on how to do this.

### **Benefits of involving the GP**

It is important to emphasise the benefits of involving the GP because the GP:

- is increasingly expected to provide general medical care to those diagnosed with HIV
- is usually the first contact for out-of-hours and emergency care
- will need to be aware of any ART prescribed so that adverse drug interactions can be avoided when other drugs are prescribed
- is in close contact with local social, counselling and support services and can therefore refer for appropriate support if required
- can diagnose, treat or refer HIV-related problems which could be overlooked if he/she is unaware of the diagnosis
- can support the whole family, but will not tell other members of the family unless the patient requests it and will not do this without discussion.

It was previously the case that people with HIV used to have all their medical care managed in the HIV specialist setting, but due to changes in funding arrangements HIV specialist services are expected to provide only HIV and HIV-related treatment and care.

### **Non-attendance for HIV test results**

Sometimes patients will not return to collect their HIV test result. This can occur whether the test result is positive or negative. There may be simple logistical reasons for this or it may be because they are worried about the impact of a positive result. There is usually a significant benefit for the patient in knowing the test result, both for those testing positive and those testing negative. The benefits to the patient of receiving a positive test result are clear, but there are also important benefits for those who test negative, eg relief of anxiety and increased motivation to use HIV preventive measures when in sexually high-risk or serodiscordant sexual relationships (where one partner is HIV-positive, the other HIV-negative).

It is good practice to have procedures in place to maximise follow-up for people who do not return

for the results of any investigation carried out in a secondary care setting. HIV test results are no different in that patient contact details should be recorded and options for contact discussed. However, due to the sensitive nature of an HIV diagnosis and its attendant social implications, it is important to record during the pre-test discussion whether the patient has agreed that the result may be shared with their GP so that appropriate follow-up can occur.



## **Providing written confirmation of results**

Patients may require a written confirmation of a negative HIV test result, eg for the purposes of employment, or for travel to a country with strict controls on admitting people with HIV. Also, patients who are diagnosed HIV-positive may request written confirmation of their HIV status – a ‘letter of diagnosis’ is usually required when applying for certain benefits, for example.

If there are sound lines of communication between primary and secondary care then such confirmations are better provided by the patient’s GP, but if you are asked to do this it is good practice to have a procedure in place for such an eventuality. This involves:

- asking to see a form of photographic identification such as a passport or driving licence both at the time the test is taken and when the result is given
- documenting the patient’s request and the form of identification both in the notes and in the letter provided
- providing a letter signed by the doctor – a copy of the patient’s laboratory test result is not appropriate
- addressing the letter to a specific individual in the organisation requesting confirmation, not in general terms such as ‘To whom it may concern’.

# SECTION 6

## Barriers to HIV testing

### IN THIS SECTION

<b>Patient concerns about HIV testing</b>	<b>60</b>
<b>Clinicians' concerns about HIV testing</b>	<b>64</b>
<b>Working with groups most at risk of HIV infection</b>	<b>66</b>

# Barriers to HIV testing

The reasons why people may not agree to test for HIV when they might for other equally serious medical conditions are many and complex. This section is intended to give the non-specialist clinician an insight into these reasons and to provide some background on what might inform a patient's decision to test, or not to test, for HIV. In so doing, it looks at common barriers for patients to HIV testing.

## Patient concerns about HIV testing

### Confidentiality

Although the 'exceptionalism' associated with HIV, and HIV testing in particular, is now being challenged many people still worry about confidentiality and fear the consequences of others finding out if they test positive. As HIV remains a highly stigmatising diagnosis in the UK these fears are often not unfounded.

Concerns about the confidentiality of HIV test results can be a barrier to seeking HIV testing or agreeing to be tested. These concerns may also

inhibit people from talking openly about personal issues, so it is important for clinicians who offer HIV testing to explore worries about confidentiality and reassure patients about local measures to protect confidentiality. If clinicians take a non-judgemental and empathic approach to different lifestyles this can help in allaying patients' fears. Ensuring that services understand and respect patient concerns about confidentiality and fears of discrimination will support and encourage:

- open discussion of, and testing for, HIV with those who may be at risk
- open discussion about safer sexual and injecting practices
- improved quality of care for people with HIV infection.

For updated guidance on confidentiality from the GMC<sup>31</sup> see its website.

see page 57 for benefits of involving the GP

## case study

### Fears about confidentiality

Mr and Mrs U are a middle aged couple who live in suburban London. They both have HIV and are on treatment. They have two teenage children; the older one is applying for medical school. They are terrified that their children, neighbours and friends might find out about their HIV. Mrs U attends an HIV clinic in central London where she has given a false name and keeps her ART in her handbag for fear of her children finding it and asking questions. She disposes of the packaging away from her home. *'I know if my neighbours found out they would not let their kids stay over at our place, and I am sure I would lose my job. I know that there are supposed to be laws to protect you but you can imagine what would happen – people wouldn't want someone with HIV serving food to their children'.*

### Learning point

- Some patients will go to enormous lengths to protect their confidentiality.

**HIV testing and insurance**

It is still widely believed by the general public that having an HIV test will adversely affect life insurance or mortgage applications and this has led to a reluctance to test for HIV. This is because people are afraid that a doctor or patient may have to declare an HIV test regardless of the result on an insurance application. However, as long ago as 1994 the Association of British Insurers (ABI) stated that a previous negative HIV test should not affect an application for insurance<sup>32</sup>. Recent joint guidelines from the ABI and BMA provide more detailed advice for doctors. Insurers should only ask applicants whether they have tested positive for HIV<sup>33</sup>.

Therefore, doctors should be guided by clinical need above all other considerations and not allow insurance concerns to compromise patient care. If an HIV test is appropriate, it should be offered and the patient reassured that negative test results will have no bearing on future life insurance applications.

Patients who ask should be informed that positive HIV test results, just like positive test results for any other serious medical condition, would have to be declared on such applications<sup>34</sup>, but this is not a complete bar to obtaining insurance or mortgages and there are companies that offer these services to people with HIV.

**Immigration issues**

Testing and counselling for HIV are free to everyone regardless of their residence status. However, any subsequent treatment for HIV is not.

There are also other exemptions from NHS charging regulations. The main ones are:

- anyone living lawfully in the UK for the previous 12 months
- anyone in legal employment in the UK for a UK-based employer
- anyone taking up permanent residence in the UK (but applicants for permanent residence will be charged until it is granted or until 12 months of lawful residence is reached)
- refugees and asylum seekers
- prisoners and immigration detainees
- full-time students (they usually must be on courses of six months or more)
- anyone whose home countries have a reciprocal health agreement with the UK.

Many people who are seeking asylum in the UK come from high prevalence countries in sub-Saharan Africa and may worry that a positive HIV test may be detrimental in their asylum case. Having HIV is not a factor that will prevent asylum being granted and asylum seekers can claim free HIV treatment from the NHS as long as their claim is current, including any appeal periods. Asylum seekers who have already accessed free treatment and whose claim is later denied are still entitled to that course of treatment free of charge and, due to a High Court decision, as of April 11 2008 may potentially be considered to be ordinarily resident in

## case study

### Asylum seeker and HIV treatment

Dr H, aged 37, from Zambia, married with three children and in the UK studying for his MRCP was referred for treatment of his hypertension. He presented with widespread seborrhoeic dermatitis and cervical lymphadenopathy. When asked if he had had any medical problems in the past, he denied anything apart from his poorly controlled hypertension.

When an HIV test was suggested, he became very anxious. He said he was very worried about the possibility of HIV, and confided that he would find it very difficult to talk to his wife about it. He also feared that if the Home Office or his employer knew he had HIV, it could have detrimental implications for

his continuing to remain in the UK. His younger sister had recently died of TB/HIV, shortly after giving birth to her first child in Zambia.

The doctor involved the HIV specialist team and the health adviser reassured Dr H that he was better off getting his HIV treated and that he was eligible for free treatment. He agreed to take the test and it was positive.

### Learning points

- HIV prevalence is greater than 15 per cent among adults from some southern African countries.
- Fear of discrimination in immigration and employment can lead to denial about HIV.
- Complex issues should be referred to the HIV specialist team for discussion.

the UK regardless of the fact that their application has failed, in which case all treatment they need for any condition will be free.

However, for those whose claim has already been rejected who were not already receiving free HIV treatment and who are not considered to meet the ordinary residence test, free HIV treatment is not available. In some cases lawyers will try to argue that a person with HIV requiring treatment should not be deported to their country of origin if ART is not available there – however such arguments are often not successful in obtaining asylum for such applicants. Some women fleeing conflict zones may have added HIV risk, having suffered sexual violence. Discussing HIV in these situations must be approached sensitively and advice can be sought and counselling available from organisations such as the Medical Foundation for the Care of Victims of Torture.

As immigration is a complex and specialist topic, anyone seeking advice on their entitlement to free NHS treatment should contact the appropriate advice services.

### Criminal prosecution of HIV transmission

Between 2001 and 2008 there were 16 prosecutions in the UK for transmitting HIV during unprotected sex. In England and Wales those found guilty were convicted of 'recklessly inflicting grievous bodily harm', under Section 20 of the Offences Against the Person Act 1861, and in Scotland of 'reckless injury'. The majority of these prosecutions have resulted in prison sentences ranging from two to ten years. It should be

see page 80 for details of national support services

borne in mind that such prosecutions are rare unless there are compelling circumstances and there is no offence of exposure to HIV. No prosecutions have been brought where transmission has not occurred.

In one case the defendant had never had an HIV test, but it was judged that he ought to have known or suspected that he had HIV. In several cases, analysis of virus samples from the complainant and defendant was used to 'prove' that the defendant infected the complainant<sup>35</sup>. However, in one case it was established that such analysis is incapable of proving conclusively that one party infected the other and the defendant was acquitted. Where, however, the strains are different, analysis can prove conclusively that one party did not infect the other<sup>36</sup>.

HIV support organisations fear that any criminal prosecution of HIV transmission increases stigma and marginalisation for people with HIV, and prevents people who may be at risk from seeking testing and care<sup>37</sup>.

These legal cases have raised concerns for clinicians and patients about their rights, responsibilities and legal obligations to disclose information to others, particularly as confidential medical records can be obtained by a court order for use as evidence in trials. These concerns are discussed in detail in a briefing paper<sup>38</sup> which outlines how decisions often have to be taken in situations of legal and ethical uncertainty.

## **Stigma**

HIV and AIDS are predominantly found in marginalised groups in society such as gay men and immigrants, or associated with behaviours such as casual sex, drug addiction, prostitution or promiscuity which may be considered immoral. HIV infection is widely known to be incurable and people are afraid of contracting it. The link between sex and illness means that people who contract HIV are often thought to have brought it upon themselves as a result of personal irresponsibility or immorality. These factors combine to create a stigma around HIV which underpins prejudice, discrimination and even violence towards people infected. Negative attitudes to HIV are widely reinforced in media coverage of the issue and are prevalent in the general population.

Stigma means that some people do not seek HIV testing or may be reluctant to agree to an HIV test, despite knowing they might be at risk. Others do not consider HIV testing because they may not be aware that they could be infected, or they do not think that they belong to a group that is vulnerable to HIV, or they have little information or understanding about HIV transmission.

Despite the availability of effective treatment in the UK which has led to people with HIV becoming less easily identifiable, very few people with HIV feel able to be open about their HIV status. Few tell employers or colleagues at work, and many do not tell even their closest family and friends. Some people do not feel able to confide in their sexual partners or spouses for fear of rejection or abuse. The isolation and fear of being 'found out' and subsequently rejected or discriminated against, can be

enormous, leading to stress and depression. In some communities, the stigma is so great that the HIV-negative members of those communities ostracise and reject the HIV-positive members.

Sometimes these fears are unfounded or exaggerated, and sharing with trusted family members and friends can provide great support. There are also voluntary and community organisations which provide support and services for people with HIV and these have helped many to cope with both the medical and social consequences of a positive HIV diagnosis.

People with HIV are now covered from the point of diagnosis by the provisions of the Disability Discrimination Act and this provides protection against discrimination in a variety of fields, including employment and the provision of goods, facilities and services. The Department of Health recognises that stigma is an important determining factor in the level of uptake of HIV testing<sup>39</sup> and has funded a number of interventions aimed at reducing the stigma surrounding HIV. One of these is the NAM publication *HIV, stigma and you*<sup>40</sup> which provides useful information on the nature and effects of HIV-related stigma.

## **Clinicians' concerns about HIV testing**

HIV is a recent phenomenon. What we now understand as AIDS was only described in the medical literature in 1981. Historically, all aspects of HIV diagnosis, treatment and care have been managed within the specialities of GUM or Infectious Diseases. Because of this, the opportunities for generalists and other specialist clinicians to gain experience in diagnosing HIV, offering testing or understanding the concerns of people with HIV have been limited. This was, in part, a pragmatic response to the way in which HIV and AIDS were represented in the media in the early days of the epidemic which created a stigma around HIV infection, but this 'exceptional' approach to HIV has made clinicians hesitant about recommending HIV testing and has led to clinicians being deskilled. This has inadvertently perpetuated the secrecy, discrimination and stigma surrounding an HIV diagnosis. This section examines the common barriers that clinicians might encounter to offering HIV testing to patients.

### **Fear of embarrassing the patient**

Some clinicians are reluctant to offer HIV testing to people from groups most at risk from HIV in situations where there are no overt signs of infection in case they are perceived as making a judgement about that person's sexual orientation, lifestyle or immigration status. Equally, when patients do not have obvious risks of infection this potential for embarrassment has prevented discussion of HIV where there are clinical signs of infection.

A useful rule of thumb is that an embarrassed doctor leads to an embarrassed patient so it is best to be open about the reasons for offering an HIV test. Where indicated by symptoms, simply state that when these

## case study

**Late diagnosis**

Mr D, a 66-year-old married man was admitted to hospital with diarrhoea, weight loss, weakness and confusion. Over the preceding six months he had been admitted to hospital on two occasions with similar symptoms and investigated extensively for occult malignancy without a diagnosis being made and no HIV risk assessment was undertaken. On examination he was cachectic, disorientated and febrile, with a small pigmented lesion on his shin.

An HIV test proved positive and further investigations showed he had CMV encephalopathy, CMV retinitis and cutaneous Kaposi's sarcoma. His CD4 count was 60 cells/mm<sup>3</sup>. Mr D made a full neurological recovery after receiving antiretroviral therapy.

**Learning point**

- If the symptoms could indicate HIV infection it is important to offer an HIV test even if a risk assessment has not been done.

symptoms are present, the recommendation is that an HIV test is carried out. Citing the authority of the *UK National Guidelines for HIV Testing 2008* and saying that this is part of good medical practice can help to reassure the patient that no judgements are being made about any aspect of their personal circumstances.

**Lack of time**

In many secondary care settings such as outpatient clinics, time can be at a premium and many clinicians fear being drawn into protracted discussions if they suggest an HIV test. Once again, a clear statement of the clinical reasoning for the offer is helpful here, and reassuring the patient about the confidentiality of the service and the lack of repercussions from a negative result can help to reduce anxiety.

Written information explaining the test is also helpful as it gives the patient and the clinician something to work through and provides a neat framework for the discussion.

**Perceived lack of specialist HIV counselling skills**

Talking about HIV should not be seen as 'special'. Clinicians are used to talking about sensitive issues and HIV should not be thought of differently. Some clinicians think that in-depth counselling is required prior to offering an HIV test. This is no longer the case and a short, focused pre-test discussion similar to that before any test which may result in a potentially life-altering diagnosis for a patient is recommended. Sections 4 and 5 on pre- and post-test discussion provide helpful approaches to discussing HIV with patients.

**'The patient won't cope with a dual diagnosis'**

Some clinicians worry that a patient will become depressed or suicidal if they find out that they have HIV, particularly if they are presenting with a



## case study

### Men who have sex with men

Mr P, a 55-year-old man presented to a sexual health clinic asking for routine screening. He was originally from India, but had lived in the UK for most of his adult life. He was asymptomatic and gave a sexual history of a long-term female partner and a couple of casual female partners in the last few years. Men who attend sexual health clinics are routinely asked if they have ever had sex with men. He denied this.

He saw a nurse and had a routine screen for STIs, including an HIV test. The result was positive. When the health adviser gave Mr P the positive result at follow-up, he disclosed that he was gay, with a long-term male partner

and a few casual male partners over the past few years. He attended for his initial appointment and the testing of partners was arranged. However Mr P was very concerned as he was well known in the local community with business interests locally. He decided to access HIV care in a different area, as anonymity was very important to him. This was facilitated for him by the clinic to ensure the appropriate handover of information.

### Learning point

- Some men who have sex with men may initially not volunteer or be reluctant to disclose information about their sexual life.

serious condition and do not think that they are at risk from HIV. Although no patient welcomes a diagnosis, the situation for people with HIV in the UK is much more optimistic than it was 10 years ago, and it is important to emphasise that the first condition can only be effectively treated if the HIV is managed well.

### 'The patient doesn't consider themselves at risk'

Knowledge about HIV in the UK is deteriorating. In 2005 a survey conducted for the National AIDS Trust indicated that people in the UK knew less about HIV compared to five years previously<sup>41</sup>. The 2007 results of the same survey show that the trend is continuing<sup>42</sup>. Many people think that as HIV in the UK is largely confined to particular groups, such as 'gay men, drug users and people from Africa' they have no reason to consider themselves at risk.

### Working with groups most at risk of HIV infection

HIV in the UK is most common in certain population groups:

- men who have sex with men
- people from sub-Saharan Africa or who have lived there
- injecting drug users.

Members of all these groups may already feel marginalised or stigmatised in UK society. The stigma and discrimination associated with HIV can exacerbate this.

### Men who have sex with men

This term is used to describe both men who identify as gay, and also

those who have sexual encounters with other men without considering themselves to be homosexual. While gay men may have a sense of belonging and access to gay-oriented culture, other men who have sex with men often see themselves as bisexual or even heterosexual, are sometimes married, and may not be willing to be open about their same-sex encounters.

### **African communities**

Fear and prejudice against HIV is often very high in African communities, with resultant stigma and secrecy. Many people from high-prevalence countries will know of family members or friends who are living with, or have died from, HIV. This is particularly true for people from southern Africa as adult HIV prevalence rates are in the order of 15-25 per cent in countries like Zimbabwe, Zambia, Botswana and South Africa. In some families HIV may affect both parents and some of the children, creating major family needs.

When offering HIV testing to people from this group, it is essential to present information in a culturally sensitive way. Worries about employment and immigration and asylum issues can compound anxiety about confidentiality and disclosure of HIV status. The more medical aspects of HIV may be difficult for patients who do not have English as a first language, or come from countries such as conflict/post-conflict settings where they may have had limited opportunities for formal education.

### **case study**

#### **Cultural factors affect how a patient deals with their diagnosis**

Mrs M was a 45-year-old Nigerian hairdresser/beautician. She was separated from her husband and had lived in the UK for five years with her three daughters. She presented with a severe bacterial pneumonia due to *Mycoplasma pneumoniae*, requiring hospital admission. On examination the doctor noticed that she had some scarring on her trunk compatible with previous herpes zoster. She made a good recovery from her pneumonia and the doctor suggested HIV testing, to which she agreed. The result was positive and her CD4 count was 190 cells/mm<sup>3</sup>. She was referred to the HIV team who initiated ART, carefully explaining the regimen, potential side-effects and the need to adhere rigorously

to her treatment. She was given information about a local support group for women with HIV and an appointment to see the HIV team in outpatients in two weeks time.

When she was seen in outpatients two months later, the repeat CD4 count was 160 cells/mm<sup>3</sup> and her viral load was still high. She admitted she had not been taking treatment because she had 'great faith in God and he is looking after her'. She had confided to a pastor at her church who had prayed with her and was confident that she would get better without treatment.

#### **Learning point**

- Some patients' religious and cultural beliefs will affect their understanding of HIV.

Cultural, social and religious views may also affect understanding of and beliefs about illness and treatment, so it is important to check patients' understanding of key issues, as many may not remember a great deal of what you have told them during the consultation. Cultural and religious beliefs may also affect how people will cope with a diagnosis of HIV. It is important to explore these beliefs as they may affect future treatment and adherence and to be open and non-judgmental when discussing these issues. It is often helpful to have patient leaflets available which cover key issues about HIV and give contact details of local support groups and HIV services.

## case study

### Injecting drug user

Mr Z, aged 29, originally from Spain but now living in the UK, presented in ED with a large groin abscess and evidence of recent injecting. He was thin, febrile and agitated. He was of no fixed abode and spoke little English. When an interpreter was found it was established that he had recently come to the UK following family problems and had been injecting drugs for many years. He denied ever having had an HIV test but agreed to undergo testing. The HIV test was positive, with a CD4 count of 220 cells/mm<sup>3</sup>, a viral load of 15,000 copies/ml and hepatitis C antibody was detectable.

### Learning point

- HIV and hepatitis C are common in people who inject drugs, especially in people who come from countries which have been slower to adopt safe injecting programmes.
- People diagnosed with HIV in any setting should be referred for specialist evaluation within two weeks according to the national *Standards for HIV Clinical Care*.
- Improved survival of patients with HIV means that hepatitis C co-infection should be actively sought and treated to prevent progression to cirrhosis and hepatocellular carcinoma.
- Co-infected patients should be referred to the HIV specialist team as soon as possible for assessment for ART regardless of their CD4 count and viral load.

### Injecting drug users (IDUs)

Those who have acquired HIV through injecting drugs (even if they no longer use drugs) will be aware of being doubly stigmatised; as drug users they are a socially excluded group, and this may be compounded by a positive HIV status. Those who have not wished to access support, or who have been unable to, may be locked in a cycle of problems as they try to fund their drug use. Dependent drug use may restrict the ability to attend appointments or to take medication regularly. In some cases, HIV may not be a priority in comparison to the daily problems associated with drug dependence.

### Patients with no obvious risk factors

Although HIV is statistically more likely to be found in people in the groups mentioned above, HIV can be seen in patients who have no obvious risk factors or who deny any HIV-associated risk behaviour. Some things that happened many years ago may have been forgotten, or the patient may be in denial about them. These could be an isolated episode of injecting drug use, receiving a blood transfusion or other invasive medical procedure in an area of high

## case study

### Patient with no obvious risk factors

Mrs G was 58 years old, overweight and alcohol dependent. She had been referred for assessment prior to admission for detoxification from alcohol abuse. Routine blood tests showed abnormal liver function tests, anaemia and neutropenia. Her doctor sent off further tests having obtained consent and was surprised when she was also found to have syphilis, hepatitis B and HIV. She had never injected drugs and had a long-term

boyfriend. Her boyfriend had been on several golfing holidays in South Africa where, unbeknownst to her, he had had unprotected sex with commercial sex workers.

### Learning points

- Some people have no obvious risk factors for HIV infection.
- People who think that they have no HIV risk factors may need specialist counselling and support to help them cope with a diagnosis.

HIV prevalence or having sexual contact with a person from an area of high HIV prevalence. Others may be genuinely unaware that they have been exposed to HIV.

While rare, such instances do occur and it is important to offer an HIV test where clinically indicated. The issues raised by such cases highlight the need to involve the HIV specialist team who can provide guidance on how to give a positive result sensitively and ensure that partner notification is dealt with appropriately.

## case study

### Patient suspects they might have HIV

Mrs M was a 27-year-old woman attending antenatal clinic for her first pregnancy. She was found to be HIV-positive during routine antenatal screening, and enrolled in a prevention-of-mother-to-child-transmission programme. She suspected that she might have acquired HIV from a previous boyfriend who injected drugs, but refused to tell her husband, because she said he would blame her and was likely to be violent towards her.

### Learning points

- HIV stigma is so great in some communities that HIV-infected people may prefer to conceal their diagnosis from partners and family.
- Specialist HIV services are best placed to deal with the sensitive issues raised.

### The patient may suspect that he/she has HIV, but may not volunteer information

Some people, particularly from groups where HIV is prevalent, are very aware of HIV and may have partners, friends or family who are living with HIV. It may be something that they often worry about, but which they are hesitant to mention, especially if they are attending medical services to which they do not consider HIV relevant, eg family planning or gynaecology clinics. Asking probing questions, such as, 'Is there anything particular that you have been worrying about?' or 'Is there anything that you think could be causing this problem?' and reassuring them of the confidentiality of your service may elicit anxieties about HIV.



# SECTION 7

## Annexes

### IN THIS SECTION

<b>Annexe A: Advice on testing without consent</b>	<b>72</b>
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<b>Annexe B: Post-exposure prophylaxis (PEP)</b>	<b>73</b>
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<b>Annexe C: The patient diagnosed very late</b>	<b>75</b>
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# Annexes

## Annexe A: Advice on testing without consent

The situations in which you might consider testing a patient for HIV who lacks the capacity to consent are most likely to arise in inpatient situations, eg where the patient has been admitted to the ICU or via the ED and is very ill, or in and out of consciousness. In England, the provisions of the Mental Capacity Act 2005<sup>43</sup> apply, and in Scotland this is covered by the Adults with Incapacity Act (Scotland) 2000<sup>44</sup>. In the first instance it is important to determine whether incapacity to consent to testing is temporary, fluctuating or permanent. Where incapacity is temporary, eg the patient is recovering from anaesthesia or under the influence of alcohol or drugs, you should wait until capacity is regained unless there is a compelling reason why this would not be in the patient's best interest. If capacity is fluctuating, eg in dementia, you should use a period of capacity to establish the patient's views on HIV testing and record these for review to establish that their views are consistent and can be relied on.

### Testing the unconscious patient without consent<sup>48</sup>

Where a diagnosis of HIV would lead to a change in management of the patient's condition, the decision should be taken by the patient's consultant and should be discussed with the Infectious Diseases, Medical Microbiology or GUM teams.

- Document in the notes that the test is being done for direct patient care reasons
- There is no legal obligation to seek permission from the patient's relatives, or inform them that the test is being performed
- If tested for HIV, the patient should be informed of the result in confidence once they are sufficiently alert to understand and remember the result
- If positive, seek immediate advice from the specialist team.

Testing without the patient's consent is only justified in rare circumstances, and if it will affect the immediate care of the patient. Guidance from the BMA on assessing capacity should be consulted if this is considered<sup>45,46,47</sup>. There are two main sets of circumstances under which testing without consent may need to be considered.

### Patients without the mental capacity to consent

There may be cases when a patient is unable (eg due to severe depression or cognitive impairment) or unwilling (eg due to mania or psychosis) to give consent, but it is in his/her best interest to be tested in order to provide optimal medical care. When considering HIV testing without consent, the clinician must ensure that a clear reason for testing is established, and that testing is of specific benefit to the patient's clinical management.

### The unconscious patient

The same principles should be taken into account when HIV testing is being considered

in the unconscious patient. Whenever testing without consent is being explored, full consultation with the medical and/or mental health team and clear documentation of the rationale and decisions involved is recommended.

## **Annexe B: Post-exposure prophylaxis (PEP)**

### **PEP for occupational exposure (needlestick injuries)**

PEP is the emergency use of antiretroviral therapy (ART) to prevent transmission when a person has had a high risk exposure to HIV, eg following a needlestick injury where the source person is known to have HIV. It is important to act quickly as, if PEP is to be given, it should be given as soon as possible after the exposure (within hours) to maximise effectiveness. PEP is generally not recommended beyond 72 hours after exposure.

If the source patient is of unknown HIV status, it is recommended that they are tested urgently for HIV. The use of a rapid testing device (or point of care test) may be useful where obtaining a laboratory test result will be delayed. Informed consent must be obtained from the patient in this case, as for any other HIV test, and if the patient does not wish to know the result it is possible to test them without documenting the result in their notes.

PEP can be unpleasant to take as the drugs have side-effects. This needs to be balanced against the risk of transmission after a given type of exposure:

- 3/1000 for percutaneous exposure
- less than 1/1000 for mucocutaneous exposure.

Exposure of HIV-infected blood to intact skin is not considered to pose any risk of infection.

In any hospital setting there will be local arrangements for urgent advice about occupational exposure and PEP as well as agreed protocols, involving reference to appropriate specialists and out-of-hours cover arrangements. An initial risk assessment of the exposure incident should be made by the designated healthcare worker responsible for PEP, taking into account the nature of the exposure and the viral load of the source patient.

The exact choice of drug combination requires expert guidance. If there is information about the source patient's virus, this will influence the choice of PEP. DH guidelines should be consulted for the latest recommended PEP starter regimen<sup>19</sup>. The medication is usually taken for four weeks but can have significant side-effects. Because of the high risk of side-effects with PEP, many doctors routinely prescribe an anti-emetic such as cyclizine and an anti-diarrhoea drug such as lomotil.

Some people who have been prescribed ART prophylaxis report not taking the fully prescribed course, so counselling and adherence support should be available for the exposed healthcare worker.



## **The unconscious source patient in a needlestick injury**

In the event of a needlestick injury or similar accident, it is illegal to test an unconscious source patient for HIV for the benefit of another individual, eg to reassure the exposed healthcare worker that they are not at risk of acquiring HIV, or to avoid taking potentially toxic post-exposure prophylaxis for four weeks. This is the subject of ongoing public debate, and a useful analysis of the issues can be found in a December 2007 editorial by White in the journal *Anaesthesia*<sup>49</sup>.

## **Post-exposure prophylaxis following sexual exposure (PEPSE)**

In the instance of a condom rupturing (or not being used), it is considered appropriate to offer PEPSE to the uninfected sexual partner of someone known to have HIV. PEPSE following potential sexual exposure to HIV is only recommended when the individual presents within 72 hours of exposure, and PEPSE should be given as early as possible within this timeframe. A course of PEPSE lasts four weeks.

PEPSE is available from HIV and GUM clinics and from emergency departments when these are closed. Anyone presenting for PEPSE needs to be assessed according to the BASHH UK guideline for the use of PEPSE<sup>20</sup> which states that:

‘...a risk vs. benefit analysis should be undertaken for every individual presenting following an exposure and the decision to initiate PEP made on a case-by-case basis. This should consider both the risk of transmission according to the coital act and the risk of the source being HIV-positive. Consideration should be given to the possibility of the presenting individual having already been infected with HIV, and the ability to adhere to and tolerate the proposed antiretroviral drug regimen. The wishes of the individual should be considered at all times.’

PEPSE is recommended for receptive anal sex when the source individual is from a group or area of high prevalence, and for both receptive and insertive anal and vaginal sex if the source individual is known to be HIV-positive<sup>20</sup>. Where the HIV status of the source is unknown, PEPSE is considered for receptive anal sex, but not recommended for receptive vaginal sex.

## **PEPSE following sexual assault**

PEPSE should also be considered following sexual assault, and police guidelines<sup>50</sup> recommend PEPSE for receptive vaginal and anal sex if the source individual is known to be HIV-positive. If the source is from an area of high prevalence (greater than 10%), PEPSE is recommended for receptive anal sex and considered for receptive vaginal sex. In line with the BASHH guideline, where the HIV status of the source is unknown, PEPSE is considered for receptive anal sex, but not recommended for receptive vaginal sex unless there is trauma or bleeding.

## Annexe C: The patient diagnosed very late

### The dying patient

The use of ART has meant that death as result of HIV infection has become much less common. Nevertheless, deaths still occur, and the secondary care team may be involved in decisions regarding care as death approaches. With ART it is harder to define when a patient is terminally ill because, given time, there can be recovery of immunity if ART is commenced or the regimen altered. However, until that happens the patient remains vulnerable to opportunistic infections. With this uncertainty about outcome, there is a need to integrate palliative and curative approaches to care, and the goals of HIV palliative care need to be redefined.

### Involvement of other healthcare professionals

The course of advanced HIV disease may be more 'up and down' than other conditions requiring palliative care. Continuity and communication are extremely important in palliative care, and general practice, rather than secondary care, is often best-suited to providing these. The patient should be offered the support and involvement of palliative services and community nursing if appropriate. Some GPs can harness the support of specialist community nurses in HIV care. Hospice care may be needed. Respite care and symptom control are currently the most important indications for admission.

### The following advice is taken from the GMC website's FAQ's section

#### Questions relating to the guidance on disclosure after a patient's death

(see paragraph 30 of *Confidentiality: Protecting and Providing Information 2004*)

#### Q18 Is it true that the duty of confidentiality continues after the patient's death?

Yes, but the extent to which information may be disclosed will depend on the circumstances. *Confidentiality: Protecting and Providing Information 2004* sets out criteria you need to consider. But there are circumstances in which you should disclose information, eg:

- to assist a Coroner, Procurator Fiscal or other similar officer with an inquest or fatal accident inquiry (see also paragraph 69 of *Good Medical Practice 2006*)
- to National Confidential Inquiries or other clinical audit or for education or research. Information should be anonymised wherever possible
- on death certificates. You must complete death certificates honestly and fully.

## **If a patient dies with HIV**

The issue of death certification for people who have died of HIV-related illness can be complicated. It is commonly accepted that confidentiality persists after death and there are ethical considerations regarding such confidentiality when a patient or their relatives do not wish HIV to be recorded as a cause of death due to the stigma surrounding it. However, there is a clear legal requirement to indicate on the death certificate any underlying condition which may have contributed to a patient's death, and while this may potentially cause conflict with a patient's or their relatives' wishes the clinician's duty to comply with the law is clear and unambiguous.

Since the Shipman Enquiry, and with the rise in deaths from hospital acquired infections, it has become clear that this is an area which is under renewed scrutiny. Recently the English CMO emphasised this in a recent letter on healthcare associated infections and death certificates, reminding clinicians of the importance of complying with statutory requirements on death certification<sup>51</sup>.

# SECTION 8

## Useful sources of further information

### IN THIS SECTION

<b>Websites for clinicians</b>	<b>78</b>
<b>Websites for patients</b>	<b>79</b>
<b>Leaflets for patients</b>	<b>79</b>
<b>Organisations for support and information</b>	<b>80</b>

## Useful sources of further information

### Websites for clinicians

#### **British Association for Sexual Health and HIV (BASHH)**

[www.bashh.org](http://www.bashh.org)

Professional organisation for GU medicine that produces sexually transmitted infections treatment guidelines.

#### **British HIV Association (BHIVA)**

[www.bhiva.org](http://www.bhiva.org)

Regularly updated guidelines for treatment of HIV-infected adults with ART, and associated guidelines (HIV in pregnancy, HIV and hepatitis co-infection, adherence support).

#### **British Infection Society (BIS)**

[www.britishinfectionsociety.org](http://www.britishinfectionsociety.org)

Wide ranging infection interests including HIV, hepatitis and opportunistic infections. Includes summary and links to guidelines of best infection practice and HIV-related guidelines produced jointly with BASHH, BHIVA and other groups

#### **Children's HIV Association of the UK and Ireland (CHIVA)**

[www.chiva.org.uk](http://www.chiva.org.uk)

Contains articles and protocols on treatment and care of HIV-infected children and information on the Children's HIV National Network (CHINN).

#### **Drug interactions**

[www.hiv-druginteractions.org](http://www.hiv-druginteractions.org)

An HIV pharmacology resource for healthcare professionals and scientific researchers with the latest publications on drug interactions.

#### **Health Protection Agency**

[www.hpa.org.uk](http://www.hpa.org.uk)

Up-to-date epidemiology figures for HIV and other infections in the UK, including graphs and slides that can be downloaded and *CDR Weekly*, an electronic epidemiological bulletin.

### Websites for patients

#### **AVERT (AIDS education and research)**

[www.avert.org](http://www.avert.org)

Abundant information on HIV-related education, prevention and care, including information for young people, statistics and information about transmission, treatment and testing.

#### **NAM**

[www.aidsmap.com](http://www.aidsmap.com)

A wealth of information on HIV and ART, including updates on the latest research findings.

#### **HIV i-base**

[www.i-base.info](http://www.i-base.info)

HIV information for healthcare professionals and HIV-positive people including information on HIV treatment guidelines, answers to HIV treatment questions and materials for advocacy.

#### **Patient plus**

[www.patient.co.uk/showdoc/40025264/](http://www.patient.co.uk/showdoc/40025264/)

Information on HIV post-exposure prophylaxis which includes information on prescriptions, monitoring and follow-up.

### Leaflets for patients

#### **NAM Patient Information Booklets**

Plain English information on key treatment topics and other HIV-related issues.

[www.aidsmap.com/cms1187580.asp](http://www.aidsmap.com/cms1187580.asp)

#### **HIV therapy NAM (2008)**

Information for those considering starting antiretroviral therapy.

[www.aidsmap.com/files/file1000889.pdf](http://www.aidsmap.com/files/file1000889.pdf)

#### **HIV and TB NAM (2006)**

Information on HIV/TB co-infection. Deals with treatments and drug interactions.

[www.aidsmap.com/files/file1000888.pdf](http://www.aidsmap.com/files/file1000888.pdf)

## ***HIV, stigma and you NAM (2006)***

Information on how to deal with stigma and discrimination if it is encountered in everyday life.

[www.aidsmap.com/files/file1001097.pdf](http://www.aidsmap.com/files/file1001097.pdf)

## ***AIDS and HIV information AVERT (2007)***

Basic information on a wide range of issues including HIV and AIDS help lines, guide to HIV testing, treatment, STIs, and pregnancy.

[www.avert.org/help.htm](http://www.avert.org/help.htm)

## ***HIV: Looking after your sexual health fpa (2007)***

An information leaflet about HIV and HIV testing for the general public.

[www.fpa.org.uk/attachments/published/150/PDF%20HIV%20April%202007.pdf](http://www.fpa.org.uk/attachments/published/150/PDF%20HIV%20April%202007.pdf)

## **Organisations for support and information**

There may be local organisations accessible to you that are working with people with HIV. Below are listed just a few national organisations, which may provide you the means of identifying local ones:

### **Sexual health information line**

0800 567 123 (calls may be charged from mobile phones)

24-hour, free, confidential helpline for anyone concerned about HIV or sexual health. Translation services are available and can provide details of local HIV organisations.

### **Terence Higgins Trust**

[www.tht.org.uk](http://www.tht.org.uk)

A large charitable organisation with support services in many British towns and cities, THT produces a wide range of written resources on HIV prevention and living with HIV.

THT Direct helpline: 0845 1221 200

Monday to Friday 10am - 10pm, Saturday and Sunday 12 noon - 6pm.

<http://www.tht.org.uk/howwecanhelpyou/needhelpnow/thtdirect/>

### **Positively Women**

[www.positivelywomen.org.uk](http://www.positivelywomen.org.uk)

020 7713 0222

Monday to Friday, 10am - 1pm and 2pm - 4pm

Women living with HIV answer the helpline and will ring back free of charge.

A registered charity which offers a range of peer support, advice, information and advocacy services for HIV-positive women.

### **African AIDS Helpline**

[www.blackhealthagency.org.uk/index.php/Section16.html](http://www.blackhealthagency.org.uk/index.php/Section16.html)

0800 0967 500

Monday to Friday (except bank holidays), 10am - 6pm (Answerphone service available outside these hours).

Languages available: English, French, Portuguese, Luganda, Shona and Swahili.

### **The Medical Foundation for the Care of Victims of Torture**

[www.torturecare.org.uk](http://www.torturecare.org.uk)

The only organisation in the UK dedicated solely to the treatment of torture survivors. It has four offices, in London, Manchester, Newcastle-upon-Tyne and Glasgow.

See website for full contact and service details.





# SECTION 9

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# SECTION 10

## Subject index



# Subject index

**Notes: page numbers suffixed by ‘f’ indicate figures, ‘i’ indicate illustrations.**

## A

- abortion services *see*
  - pregnancy termination services
- abscess
  - presentation at ENT clinics 43
  - presentation at neurology clinics 33
  - presentation at respiratory clinics 30
- acne, presentation at dermatology clinics 35
- Adults with Incapacity Act (Scotland) 2000*, advice
  - on testing without consent 72
- African communities 11, 67-68
- AIDS-related dementia *see* HIV encephalopathy
- anaemia 13
  - presentation at haematology clinics 41
- anal cancers, presentation at oncology clinics 39
- antnatal clinics 69
  - HIV-related presentations 40
  - how to offer an HIV test 22
  - point of care testing 21
  - routine screening 18, 22
- antibody test *see* testing (HIV antibody test)
- antiretroviral therapy (ART) 10, 12
  - CD4 cell counts 14
  - in children 47
  - GPs 57
  - viral load 15
- aphthous ulceration, presentation at ENT clinics 43
- areas with high HIV prevalence
  - African communities 67-68
  - PEPSE 74
  - routine screening 20
- aspergillosis, presentation at respiratory clinics 31, 32
- Association of British Insurers 61
- asylum seekers 28
  - barriers to HIV testing 61-62
- asymptomatic HIV infection 13
- auscultation 29

## B

- bacterial infections 14
  - presentation at dermatology clinics 35
  - presentation at emergency departments 27
  - presentation at gastroenterology clinics 37
  - presentation at neurology clinics 33
  - presentation at respiratory clinics 31
- bad news 54, 56
- barriers to HIV testing 60-69
- behaviour change 54
- blood donation services, routine screening 19, 20
- British Association for Sexual Health and HIV (BASHH) 78
  - PEPSE guideline 19, 27, 74
  - point of care testing guideline 21
- British HIV Association (BHIVA) 78
- British Infection Society (BIS) 78

## C

- Campylobacter* species, presentation at
  - gastroenterology clinics 37
- cancers *see also specific tumours*
  - presentation at oncology clinics 39
- candidiasis *see also* oesophageal candidiasis;
  - oral candidiasis; vaginal candidiasis
  - common in the immunocompromised 14
  - presentation at dermatology clinics 35
  - presentation at respiratory clinics 31
- Castleman's disease, presentation at oncology clinics 39
- CD4 cell counts 14
  - asymptomatic HIV infection 13
  - late diagnosis 12
  - Mycobacterium avium-intracellulare* 31
  - oesophageal candidiasis 37
  - PCP 29
  - primary HIV infection 44
  - tuberculosis 30
  - viral load and 14, 15

- 
- cerebral toxoplasmosis, presentation at emergency departments 27
- 
- cervical cancers  
 presentation at obstetric clinics 40, **40i**  
 presentation at oncology clinics 39
- 
- cervical lymphadenopathy *see* lymphadenopathy
- 
- charges for HIV treatment 61-62
- 
- chest infections, presentation at respiratory clinics 31-32
- 
- child health clinics, HIV-related presentations 46-48
- 
- Children's HIV Association (CHIVA) 47, 78
- 
- Children's HIV National Network (CHINN) 47, 78
- 
- cholangitis, presentation at gastroenterology clinics 37
- 
- chronic parotitis, presentation at ENT clinics 43
- 
- clinical nurse specialists 56
- 
- clinicians' concerns about HIV testing 13, 18, 64-66
- 
- Clostridium difficile*, presentation at gastroenterology clinics 37
- 
- CMV *see* cytomegalovirus
- 
- colorectal cancers, presentation at oncology clinics 39
- 
- communication  
 how to offer an HIV test 22-23  
 people who suspect they have HIV 69
- 
- community acquired bacterial pneumonia,  
 presentation at emergency departments 27
- 
- condoms, rupture 74
- 
- confidentiality 56, 60  
 barriers to HIV testing 60  
 death of patients 75  
 infected healthcare staff 66  
 prosecution of HIV transmission 63  
 written confirmation of test results 58
- 
- Consent*, GMC guidance 51
- 
- contact details 51, 57
- 
- cost-effectiveness  
 screening 12  
 treatment 11
- 
- cough, presentation at respiratory clinics 29, 30, 32
- 
- counselling *see* pre-test discussion
- 
- countries with high HIV prevalence  
 barriers to offering an HIV test 61-62  
 how to offer an HIV test 22-23  
 routine screening 20, 28, 36
- 
- criminal prosecution of HIV transmission 62-63
- 
- cryptococcal meningitis  
 presentation at emergency departments 27  
 presentation at neurology clinics 33  
 presentation at respiratory clinics 31  
 symptomatic (AIDS-defining) HIV infection 14
- 
- cryptosporidiosis  
 as cause of diarrhoea 37  
 symptomatic (AIDS-defining) HIV infection 14
- 
- cytomegalovirus  
 presentation at neurology clinics 33  
 presentation at ophthalmology clinics 42  
 presentation at respiratory clinics 31  
 retinitis 42, **42i**, 65  
 routine HIV screening after differential diagnosis 19  
 symptomatic (AIDS-defining) HIV infection 14, 65
- 
- D**
- 
- death certificates 76
- 
- death of pati  
 neuropathies 33  
 presentation at haematology clinics 41
- 
- drug resistance, viral load 15
- 
- drug use programmes, routine screening 18-19, 20
- 
- drug users  
 presentation at gastroenterology clinics 38  
 routine screening 8-19, 20, 22  
 stigma 68  
 undiagnosed HIV infection 11, 68, 69
- 
- dysphagea, presentation at gastrointestinal clinics 37
- 
- dyspnoea, presentation at respiratory clinics 32
- 
- E**
- 
- embarrassment 64-65
- 
- emergency medicine  
 HIV-related presentations 26-28  
 how to offer a test 22-23
- 
- encephalopathy *see* HIV encephalopathy
- 
- English as second language 51, 54, 68
- 
- ENT clinics, HIV-related presentations 43
- 
- Entamoeba belli*, presentation at gastroenterology clinics 37
- 
- Enteraggregative Escherichia coli*, presentation at gastroenterology clinics 37
- 
- equivocal test results 55
- 
- exceptionalism of HIV 13, 60, 64
-

# SECTION 10

## F

- false positivity rates 21
- family members
  - barriers to HIV testing 63-64
  - death certificates 76
  - support 51
- fatigue, symptomatic HIV infection 14
- fertility clinics 40
- fevers *see also* pyrexia of unknown origin
  - presentation at emergency departments 27-28
  - presentation at respiratory clinics 29, 30, 32
  - symptomatic HIV infection 14
- folliculitis
  - routine testing 19
  - symptomatic HIV infection 14
- frequency of testing 21-22
- fungal infections
  - presentation at dermatology clinics 35
  - presentation at ophthalmology clinics 42
  - presentation at respiratory clinics 31

## G

- gastroenterology, HIV-related presentations 37-38
- gastrointestinal bleeding (GI), as cause of anaemia 41
- gay men *see* men who have sex with men
- General Medical Council (GMC), *Consent* 51
- genital herpes *see* herpes simplex
- genital warts, presentation at obstetric clinics 40
- Giardia lamblia*, presentation at gastroenterology clinics 37
- gingivitis, presentation at ENT clinics 43
- glandular fever, routine HIV screening after differential diagnosis 20, 44
- GPs 57
  - benefits of informing 36, 57
  - discharge summaries 32
  - record of informing 51
- gram negative bacilli, presentation at respiratory clinics 31
- Guillain Barré syndrome, presentation at neurology clinics 33, 34
- GUM clinics *see* sexual health clinics
- gynaecology, HIV-related presentations 40

## H

- haematology, HIV-related presentations 41
- haemophilia services, routine screening 19
- Haemophilus influenzae*
  - presentation at respiratory clinics 31-32
  - symptomatic HIV infection 14
- haemoptysis, presentation at respiratory clinics 30
- head and neck cancers, presentation at oncology clinics 39
- headache 33
  - symptomatic HIV infection 14
- health advisers 56
- Health Protection Agency 12
- hepatitis B/C
  - drug use 68
  - presentation at gastroenterology clinics 37-38
  - routine screening 19
  - symptomatic (AIDS-defining) HIV infection 14, 68, 69
- hepatology, HIV-related presentations 37-38
- herpes simplex
  - presentation at dermatology clinics 35
  - presentation at ENT clinics 43
  - presentation at neurology clinics 33
  - presentation at obstetric clinics 40
  - presentation at ophthalmology clinics 42
  - presentation at respiratory clinics 31
  - symptomatic HIV infection 14
- herpes zoster *see also* shingles
  - presentation at dermatology clinics 35
  - presentation at ophthalmology clinics 42
  - routine testing 19
- heterosexually acquired infection 10-11, **11i**, 36, 45, 69
- HIV
  - incidence 10-11, **10i**
  - natural history of infection 13-15
  - risks of transmission 73
  - viral load 15
- HIV antibody test *see* testing (HIV antibody test)
- HIV encephalopathy, presentation at neurology clinics 34
- HIV p24 antigen tests 20
- HIV RNA quantitative assays 21
- HIV-1/HIV-2 laboratory tests 20
- HIV-associated infections *see* opportunistic infections

HIV-related dementia *see* HIV encephalopathy  
 HIV testing guidelines *see also* UK National  
*Guidelines for HIV Testing 2008* 18, 20, 26, 39,  
 40, 44, 51, 54, 56, 65

Hodgkin's lymphoma, presentation at oncology  
 clinics 39

homosexuals *see* men who have sex with men

how often to test 21-22

how to give a test result 50-51, 54-58

how to offer an HIV test 22-23

clinicians' concerns 64-66

human papilloma virus (HPV)

presentation at obstetric clinics 40, **40i**

symptomatic (AIDS-defining) HIV infection 14

hypergammaglobulinaemia 13

## I

immigration, barriers to HIV testing 61-62

immunosuppressant therapy services, routine  
 screening 19

incapacity, advice on testing without consent 72

infants, HIV-related presentations 46-48

informed consent 50, 51

advice on testing without consent 72-73

injecting drug users

presentation at gastroenterology clinics 38

routine screening 8-19, 20, 22

stigma 68

undiagnosed HIV infection 11, 38, 68, 69

insurance, barriers to HIV testing 61

internet self tests 21

## K

Kaposi's sarcoma

as cause of diarrhoea 37

presentation at dermatology clinics 35, **35i**

presentation at emergency departments 28

presentation at ENT clinics 43

presentation at gastroenterology clinics 37

presentation at oncology clinics 39

presentation at ophthalmology clinics 42

presentation at respiratory clinics 31

routine HIV screening after differential diagnosis 19

symptomatic (AIDS-defining) HIV infection 14, 28, 65

*Klebsiella pneumoniae*, presentation at respiratory  
 clinics 31

## L

laboratory tests 20-21

late diagnosis of HIV 11-13, 12

advice 75

in a child 48

leaflets for further information 79-80

leukaemia, presentation at oncology clinics 39

liver cancers, presentation at oncology clinics 39

lung cancers, presentation at oncology clinics 39

lymphadenopathy

presentation at emergency departments 28

presentation at ENT clinics 43

symptomatic HIV infection, 14, 28

lymphoid interstitial pneumonitis, presentation at

child health clinics 46-47

lymphomas

presentation at gastroenterology clinics 37

presentation at neurology clinics 33

presentation at oncology clinics **39i**

presentation at ophthalmology clinics 42

routine screening 19

symptomatic (AIDS-defining) HIV infection 14

lymphopaenia 13

presentation at haematology clinics 41

## M

MAI *see* *Mycobacterium avium-intracellulare*

malaise

presentation at gastroenterology clinics 38

symptomatic HIV infection 14, 65

melanomas, presentation at oncology clinics 39

men who have sex with men 11, 11f, 32, 66-67

barriers to HIV testing 66

routine screening 20, 22

*Mental Capacity Act 2005*, advice on testing without  
 consent 72

mental health, giving test results 54

microsporidial keratoconjunctivitis, presentation at  
 ophthalmology clinics 42

molluscum contagiosum, presentation at

dermatology clinics 35

# SECTION 10

mononucleosis, routine HIV screening after  
differential diagnosis 20, 44

mortality

by prevention group 11f

by year 10f

late diagnosis 12

mortgages 61

mother-to-child transmission 18, 22, 48, 69

mycobacterial tuberculosis, presentation at  
dermatology clinics 35

*Mycobacterium avium-intracellulare*

as cause of anaemia 41

as cause of diarrhoea 37

presentation at gastroenterology clinics 37

presentation at haematology clinics 41

presentation at respiratory clinics 31

symptomatic (AIDS-defining) HIV infection 14

## N

NAM publications 79-80

natural history of infection 13-15

needlestick injuries 73

unconscious patients 74

neoplasms see oncology

presentation at respiratory clinics 31

neurology, HIV-related presentations 33-34

neuropathies 33

neurosyphilis 34

neutropenia 13

presentation at haematology clinics 41

new diagnoses of HIV by year 10f

night sweats

presentation at emergency departments 28

symptomatic HIV infection 14

non-attendance by patient 57

non-HIV specialist secondary settings, differential  
diagnosis of HIV 26-47

non-Hodgkin's lymphoma

presentation at oncology clinics 39

presentation at respiratory clinics 31

symptomatic (AIDS-defining) HIV infection 14

nutritional deficiency, neuropathies 33

## O

obstetrics, HIV-related presentations 40

occupational HIV exposure 73

routine screening 19

unconscious patients 74

odynophagia, presentation at gastrointestinal clinics  
37

oesophageal candidiasis see also candidiasis

presentation at gastroenterology clinics 37

symptomatic (AIDS-defining) HIV infection 14

oncology, HIV-related presentations 39

ophthalmology, HIV-related presentations 42

opportunistic infections

CD4 cell counts 14

neuropathies 33

presentation at emergency departments 28

opt-out testing see routine screening

oral candidiasis see also candidiasis

common in the immunocompromised 14

presentation at antenatal clinics 48

presentation at dermatology clinics 35

presentation at emergency departments 28

presentation at ENT clinics 43

presentation at gastroenterology clinics 37

oral hairy leukoplakia

presentation at ENT clinics 43, **43i**

presentation at respiratory clinics 32

symptomatic HIV infection 14

organ transplant services, routine screening 19, 20

organisations for further information 80-81

oropharyngeal cancers, presentation at oncology  
clinics 39

overseas travel

heterosexually acquired infection 10-11

HIV-related presentation 44, 45

people with no obvious risk factors 68-9

written confirmation of test results 58

## P

p24 antigen 13, 20

Paediatric European Network for the Treatment of  
AIDS (PENTA) 47

paediatrics, HIV-related presentations 46-48

parasitic infections, presentation at respiratory  
clinics 31

- 
- parotitis  
 presentation at child health clinics 46, **47i**  
 presentation at ENT clinics 43
- 
- partners of people at high risk of HIV, routine screening 20, 22, 48, 56
- 
- PCP *see* Pneumocystis pneumonia
- 
- people from higher risk groups 20, 23, 54, 66-69
- 
- people with high risk partners, routine screening 20, 22, 48, 56, 57
- 
- people with no obvious risk factors 68-9
- 
- people who suspect they have HIV 69
- 
- PEPSE *see* post-exposure prophylaxis following sexual exposure (PEPSE)
- 
- pityrosporum folliculitis, presentation at dermatology clinics 35
- 
- PML *see* progressive multifocal leucoencephalopathy
- 
- Pneumocystis pneumonia 14  
 presentation at emergency departments 27, 32  
 presentation at obstetric clinics 48  
 presentation at respiratory clinics 29, **29i**, 31, 32  
 symptomatic (AIDS-defining) HIV infection 14, 67
- 
- point of care testing 21  
 in emergency medicine 27  
 occupational health services 73
- 
- post-exposure prophylaxis following sexual exposure (PEPSE) 19  
 advice 74  
 in emergency departments 27  
 RNA assays 21  
 sexual assault 74
- 
- post-exposure prophylaxis (PEP), advice 73
- 
- post-test discussion 54-57  
 HIV-negative results 54-55  
 HIV-positive results 55-57
- 
- pre-test discussion 12, 18, 50-51
- 
- pregnancy termination services, routine screening 18
- 
- primary cerebral lymphoma, presentation at neurology clinics 33
- 
- primary HIV infection 13  
 diagnostic tips 44-45  
 RNA assays 21
- 
- progressive multifocal leucoencephalopathy  
 presentation at neurology clinics 33, **34i**  
 symptomatic (AIDS-defining) HIV infection 14
- 
- prosecution of HIV transmission 62-63
- 
- protozoal infections  
 presentation at gastroenterology clinics 37  
 presentation at ophthalmology clinics 42
- 
- Pseudomonas aeruginosa*, presentation at respiratory clinics 31
- 
- psoriasis  
 presentation at dermatology clinics 35, 36  
 symptomatic HIV infection 14
- 
- psychiatry, HIV-related presentations 33-34
- 
- pyrexia of unknown origin *see also* fevers  
 HIV-related presentation 44
- 
- R**
- 
- rape support services, routine screening 19
- 
- rapid testing *see* point of care testing
- 
- rashes, primary HIV infection 45
- 
- reactive test results 55
- 
- referral to specialist clinics 51, 55, 56
- 
- refusal to test 51
- 
- religion 67, 68
- 
- renal cancers, presentation at oncology clinics 39
- 
- repeat testing 21-22, 55
- 
- respiratory medicine, HIV-related presentations 29-32
- 
- retinitis 42, **42i**, 65
- 
- risk behaviour 45, 54
- 
- routine screening 12, 13  
 after HIV differential diagnosis 19-20  
 people in areas of higher prevalence 20  
 people who belong to higher risk 20  
 specific services 18-19  
 USA 12
- 
- S**
- 
- Salmonella* species, presentation at gastroenterology clinics 37
- 
- scabies, presentation at dermatology clinics 35
- 
- seborrhoeic dermatitis  
 presentation at dermatology clinics 35  
 routine testing 19  
 symptomatic HIV infection 14, **35i**
- 
- self-testing 21
-

# SECTION 10

seminoma, presentation at oncology clinics 39

seroconversion see primary HIV infection

sexual assault

- post-exposure prophylaxis following sexual exposure (PEPSE) 74
- routine screening 19

sexual health clinics

- HIV diagnostic tips 44-45
- point of care testing 21
- routine screening 18

sexual partners of people at high risk of HIV, routine screening 20, 22

sexually transmitted infections, HIV-related

- presentation 44-45

shingles see also herpes zoster 22

- presentation at child health clinics **46i**
- presentation at emergency departments 28
- symptomatic HIV infection 14

sinus infections, presentation at ENT clinics 43

social services, GPs 57

sources of further information 78-81

specialist secondary settings, differential diagnosis of HIV 26-47

stages of HIV infection 13-15

- virological/immunological/clinical associations 15f

*Standards for HIV Clinical Care* 21, 32, 36, 38

*Staphylococcus aureus*

- presentation at dermatology clinics 35
- presentation at respiratory clinics 31, 31
- symptomatic HIV infection 14

stigma 12-13, 50

- African communities 67-68
- barriers to HIV testing 63-64
- death certificates 76
- injecting drug users 68
- men who have sex with men 66-67

*Streptococcus pneumoniae*

- presentation at respiratory clinics 31-32
- symptomatic HIV infection 14

*Strongyloides stercoralis*, presentation at respiratory clinics 31

students 36, 61

sub-Saharan Africa 11

- routine screening 20
- stigma 66-67

survival rates, in children 47

symptomatic (AIDS-defining) HIV infections 14

- presentation at emergency departments 27
- presentation at oncology clinics 39

symptomatic early neurosyphilis 34

symptomatic HIV infection 14

syphilis 69

- presentation at neurology clinics 34
- presentation at ophthalmology clinics 42

## T

termination of pregnancy services 18, 40

testing (HIV antibody test)

- advice on testing without consent 72-73
- barriers 60-69
- clinicians' concerns 64-66
- different tests 20-21
- how to give results 50-51, 54-58
- how to offer 22-23, 64-66
- insurance 61
- non-attendance by patient 57
- post-test discussion 54-57
- pre-test discussion 50-51
- recommendations 18-23
- refusal by patient 51
- repeat 21-22
- self-testing 21
- stigma 12-13
- universal 20
- who can give it 18
- written confirmation 58

thrombocytopenia 13

- presentation at haematology clinics 41

time factors

- clinicians' concerns 65
- how often to test 21-22
- symptomatic HIV infection 14
- virological/immunological/clinical associations 15f

*Toxoplasma encephalitis*, symptomatic (AIDS-defining) HIV infection 14

*Toxoplasma gondii*

- presentation at neurology clinics 33, 33
- presentation at ophthalmology clinics 42
- presentation at respiratory clinics 31

travel

- heterosexually acquired infection 10-11

HIV-related presentation 44, 45  
 people with no obvious risk factors 68-9  
 written confirmation of test results 58

---

tuberculosis

presentation at emergency departments 27t  
 presentation at respiratory clinics 30, **30i**, 31  
 routine screening 19  
 symptomatic (AIDS-defining) HIV infection 14

---

**U**

*UK National Guidelines for HIV Testing 2008* 18, 20,  
 26, 39, 40, 44, 51, 54, 56, 65

unconscious patients, advice on testing without  
 consent 72-73

undiagnosed HIV infection 11

USA 12, 20

useful sources of further information 78-81

uveitis, presentation at ophthalmology clinics 42

---

**V**

vaginal candidiasis *see also* candidiasis  
 common in the immunocompromised 14  
 presentation at obstetric clinics 40

vaginal intraepithelial neoplasia, presentation at  
 obstetric clinics 40

viral infections

how to offer a test 22  
 presentation at gastroenterology clinics 37  
 presentation at ophthalmology clinics 42  
 presentation at respiratory clinics 31

viral load 15

viral warts, presentation at dermatology  
 clinics 35

---

**W**

websites for further information 78-79

weight loss

presentation at emergency departments 28  
 presentation at neurology clinics 33  
 presentation at respiratory clinics 30, 32  
 symptomatic HIV infection 14, 28, 32, 65

'window' period 13

point of care testing 21

post-test discussion 55

written confirmation of test results 58

written consent 51

---

**Y**

yeast infections, presentation at dermatology clinics  
 35





**British Association for  
Sexual Health and HIV (BASHH),  
British HIV Association (BHIVA) and  
British Infection Society (BIS)**

**UK National  
Guidelines for  
HIV Testing  
2008**

# Executive summary

- HIV is now a treatable medical condition and the majority of those living with the virus remain fit and well on treatment.
- Despite this a significant number of people in the United Kingdom are unaware of their HIV infection and remain at risk to their own health and of passing their virus unwittingly on to others.
- Late diagnosis is the most important factor associated with HIV-related morbidity and mortality in the UK.
- Patients should therefore be offered and encouraged to accept HIV testing in a wider range of settings than is currently the case.
- Patients with specific indicator conditions should be routinely recommended to have an HIV test.
- All doctors, nurses and midwives should be able to obtain informed consent for an HIV test in the same way that they currently do for any other medical investigation.

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# Writing committee

British Association for Sexual Health and HIV (BASHH)	Adrian Palfreeman
British HIV Association (BHIVA)	Martin Fisher
British Infection Society (BIS)	Ed Ong
College of Emergency Medicine	James Wardrope
Royal College of General Practitioners	Ewen Stewart
Royal College of Nursing	Enrique Castro-Sanchez
Royal College of Physicians	Tim Peto, Karen Rogstad
Royal College of Paediatrics and Child Health	Karen Rogstad
British Medical Association	Julian Sheather
Department of Health Expert Advisory Group on AIDS	Brian Gazzard, Deenan Pillay
General Medical Council	Jane O'Brien
Health Protection Agency	Valerie Delpech
Medical Foundation for AIDS & Sexual Health (MedFASH)	Ruth Lowbury, Russell Fleet
National AIDS Trust	Yusef Azad
Children's HIV Association (CHIVA)	Hermione Lyall
Society of Sexual Health Advisors	James Hardie
UK CAB	Godwin Adegbite
BASHH Clinical effectiveness group	Guy Rooney
Lay representative	Richard Whitehead

# Contents

1. Introduction	1
2. Background	2
3. Confidentiality and HIV testing	4
4. Recommendations for testing	5
4.1 Who can test?	
4.2 Who should be offered a test?	5
4.3 How often to test?	6
4.4 Which test to use?	9
5. Pre-test discussion	11
6. Post-test discussion	12
7. Suspected primary HIV infection	14
8. Appendices	15
Appendix 1. Providing written confirmation of results	15
Appendix 2. Detailed post-test discussion and partner notification	15
Appendix 3. Community-based HIV testing	16
Appendix 4. Testing where the patient lacks capacity to consent	16
Appendix 5. Testing infants, children and young people	17
Appendix 6. The source patient in a needlestick injury or other HIV risk exposure	20
Appendix 7. HIV testing and insurance	20
Appendix 8. HIV testing and criminal prosecution for HIV transmission	20
Appendix 9. Auditable standards	21
9. Acknowledgements	22
10. References	23

# Introduction

**These guidelines are intended to facilitate an increase in HIV testing in all healthcare settings as recommended by the UK's Chief Medical Officers and Chief Nursing Officers<sup>1,2,3,4</sup> in order to reduce the proportion of individuals with undiagnosed HIV infection with the aim of benefiting both individual and public health.**

Misperceptions remain regarding HIV testing that hinder increased testing. In particular, many clinicians believe that lengthy pre-test counselling is required prior to testing. These guidelines provide the information needed to enable any clinician to perform an HIV test within good clinical practice and encourage 'normalisation' of HIV testing.

For this change in approach to be beneficial and ethically acceptable, it is imperative that following a positive HIV diagnosis, a newly diagnosed individual is immediately linked into appropriate HIV treatment and care.

This guidance refers to both diagnostic testing of individuals presenting with 'clinical indicator diseases' (ie where HIV infection enters the differential diagnosis) and opportunistic screening of populations where this is indicated on the basis of prevalence data. We also include an appendix on the provision of community-based HIV testing (Appendix 3).

It must be emphasised that in the UK, HIV testing remains voluntary and confidential. This is entirely possible within any healthcare setting if these guidelines are followed.

# Background

**Whilst the availability of highly active antiretroviral therapy (HAART) has transformed the outcome for individuals with HIV infection, there continues to be significant and avoidable morbidity and mortality relating to HIV infection in the UK.**

A national audit by the British HIV Association (BHIVA) showed that of deaths occurring amongst HIV-positive adults in the UK in 2006, 24 per cent were directly attributable to the diagnosis of HIV being made too late for effective treatment<sup>5</sup>. Furthermore, it has been shown that many of these 'late presenters' have been seen in the recent past by healthcare professionals without the diagnosis having been made<sup>6</sup>. National surveillance data shows that approximately one-third of all HIV infections in adults in the UK remain undiagnosed<sup>7</sup> and that approximately 25 per cent of newly-diagnosed individuals have a CD4 count of less than 200 (an accepted marker of 'late' diagnosis).

Late diagnosis of HIV infection has been associated with increased mortality and morbidity<sup>7</sup>, impaired response to HAART<sup>8</sup>, and increased cost to healthcare services<sup>9</sup>. Furthermore, from a public health perspective, knowledge of HIV status is associated with a reduction in risk behaviour<sup>10</sup> and therefore it is anticipated that earlier diagnosis will result in reduced onward transmission<sup>11</sup>. Modelling has suggested that over 50 per cent of new infections in the US occur through transmission from individuals in whom HIV has not been diagnosed. Furthermore, modelling in the US has also suggested that routine screening for HIV infection is cost effective and comparable to costs of other routinely offered screening where the prevalence of HIV exceeds 0.05 per cent<sup>12</sup>.

All the published literature suggests that uptake of testing is increased where universal routine ('opt-out') strategies have been adopted<sup>13,14,15</sup>.

Universal HIV ('opt-out') testing means that all individuals attending specified settings are offered and recommended an HIV test as part of routine care but an individual has the option to refuse a test.

Prior to 2001, HIV testing was largely confined to individuals presenting and requesting HIV testing in GUM clinics. The uptake of testing was low and a significant proportion of HIV-positive individuals were known to remain undiagnosed. The National Strategy for Sexual Health and HIV (2001)<sup>16</sup> recommended that all attendees at GUM clinics should be offered an HIV test with clear targets for the proportion offered testing and test

uptake. Since this policy was introduced the proportion of infections which remain undiagnosed has reduced but still remains significant (25 per cent in heterosexuals, 47 per cent in men who have sex with men (MSM))<sup>7</sup>. The majority of GUM clinics now utilise a universal 'opt-out' approach to testing with high acceptability and success although the reasons why some high-risk individuals still refuse testing require further study.

In the antenatal setting, prior to 2000 uptake of HIV testing was highly variable and dependent upon healthcare worker factors rather than clinical need.

The only randomised controlled trial published to date<sup>13</sup> on testing methods showed that a universal 'opt-out' approach to HIV testing in antenatal patients was acceptable, did not cause anxiety and had a higher uptake than other methods. Assessing patients for risk merely reduced the number of patients tested and it is recognised that women who refuse antenatal testing are more likely to be HIV-positive.

The adoption of universal opt-out testing<sup>17</sup> has resulted in a dramatic improvement in antenatal testing rates and a significant reduction in the proportion of HIV infections that remain undiagnosed prior to delivery, from 18 per cent in 2000 to fewer than 10 per cent in 2006<sup>7</sup>. Furthermore the median CD4 count at HIV diagnosis of women detected through antenatal screening has been consistently higher than among other women (even after adjusting for age) and heterosexual men diagnosed with HIV. This indicates that efforts to detect HIV infection in asymptomatic individuals are likely to result in earlier diagnosis, hence reducing morbidity and mortality in diagnosed individuals as well as reducing onward transmission<sup>7</sup>.

In the USA in 2006 the Centers for Disease Control and Prevention (CDC) recommended opt-out testing for all individuals aged 13 to 64 presenting to any healthcare facility (mainly Emergency Rooms) for any reason<sup>18</sup>. Initial reports suggest that this has been successful in increasing the number of new HIV diagnoses but barriers continue to exist including legal requirements in some states regarding testing, a requirement for written consent, and lack of access for some patients to ongoing HIV treatment and care<sup>19</sup>.

In the UK, where the vast majority of patients have access to healthcare free at the point of delivery, all patients have access to a general practitioner and where there are pressures upon Emergency Departments to achieve four-hour waiting targets, we believe universal opt-out testing in all settings may not be the most feasible approach but support the use of opt-out testing in certain situations.



# Confidentiality and HIV testing

**HIV testing has historically been exceptionalised and treated differently to testing for other serious medical conditions. The outlook for individuals testing positive for HIV is now better than for many other serious illnesses for which clinicians routinely test.**

Whilst there remains stigma associated with HIV infection, this can be minimised by following the general principles of confidentiality for any medical condition as laid down by the GMC in its guidance *Confidentiality: protecting and providing information*<sup>20</sup>.

*'Patients have a right to expect that information about them will be held in confidence by their doctors. Confidentiality is central to trust between doctors and patients. Without assurances about confidentiality, patients may be reluctant to give doctors the information they need in order to provide good care.'*

The result of an HIV test (if positive) should be given directly by the testing clinician (or team) to the patient and not via any third party, including relatives or other clinical teams unless the patient has specifically agreed to this (see section on post-test discussion).

# Recommendations for testing

## 4.1 Who can test?

It should be within the competence of any doctor, midwife, nurse or trained healthcare worker to obtain consent for and conduct an HIV test.

## 4.2 Who should be offered a test?

A. Universal HIV testing is recommended in all of the following settings:

1. GUM or sexual health clinics
2. antenatal services
3. termination of pregnancy services
4. drug dependency programmes
5. healthcare services for those diagnosed with tuberculosis, hepatitis B, hepatitis C and lymphoma.

B. An HIV test should be considered in the following settings where diagnosed HIV prevalence in the local population (PCT/LA) exceeds two in 1,000 population (see local PCT data<sup>1</sup>)

1. all men and women registering in general practice
2. all general medical admissions.

The introduction of universal HIV testing in these settings should be thoroughly evaluated for acceptability and feasibility and the resultant data made available to better inform the ongoing implementation of this guideline.

C. HIV testing should be also routinely offered and recommended to the following patients:

1. all patients presenting for healthcare where HIV, including primary HIV infection, enters the differential diagnosis (see table of indicator diseases and section on primary HIV infection)
2. all patients diagnosed with a sexually transmitted infection
3. all sexual partners of men and women known to be HIV-positive
4. all men that have disclosed sexual contact with other men
5. all female sexual contacts of men who have sex with men
6. all patients reporting a history of injecting drug use
7. all men and women known to be from a country of high HIV prevalence (>1 per cent\*)
8. all men and women who report sexual contact abroad or in the UK with individuals from countries of high HIV prevalence.\*

\*for an up to date list see <http://www.unaids.org/en/KnowledgeCentre/HIVData/Epidemiology/latestEpiData.asp>

- D. HIV testing should also be routinely performed in the following groups in accordance with existing Department of Health guidance:
1. blood donors
  2. dialysis patients
  3. organ transplant donors and recipients.

### 4.3 How often to test?

Repeat testing should be provided for the following groups:

1. all individuals who have tested HIV-negative but where a possible exposure has occurred within the window period
2. men who have sex with men (MSM) – annually or more frequently if clinical symptoms are suggestive of seroconversion or ongoing high risk exposure
3. injecting drug users – annually or more frequently if clinical symptoms are suggestive of seroconversion (see section on primary HIV infection)
4. antenatal care – women who refuse an HIV test at booking should be re-offered a test and should they decline again a third offer of a test should be made at 36 weeks. Women presenting to services for the first time in labour should be offered a point of care test (POCT).

A POCT test may also be considered for the infant of a woman who refuses testing antenatally.

In areas of higher seroprevalence, or where there are other risk factors, women who are HIV-negative at booking may be offered a routine second test at 34-36 weeks' gestation as recommended in the BHIVA pregnancy guidelines<sup>21</sup>.

<sup>†</sup> Diagnosed prevalence is a good indicator of the undiagnosed prevalence in a population (ratio 2:1). All PCTs are routinely informed of the diagnosed prevalence rate by the Health Protection Agency (HPA) Survey of Prevalent HIV Diagnoses (SOPHID) data on an annual basis (further information on SOPHID data and its dissemination is available at [http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb\\_C/1201767906579](http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1201767906579)).

A diagnosed prevalence exceeding 2 in 1000, in those aged between 15 and 59, is a proxy for an undiagnosed prevalence exceeding 1 in 1000, the threshold at which routine testing is assumed to be cost effective based on the US data<sup>18</sup>.

<b>Table: Clinical indicator diseases for adult HIV infection</b>		
	<b>AIDS-defining conditions</b>	<b>Other conditions where HIV testing should be offered</b>
<b>Respiratory</b>	Tuberculosis Pneumocystis	Bacterial pneumonia Aspergillosis
<b>Neurology</b>	Cerebral toxoplasmosis Primary cerebral lymphoma Cryptococcal meningitis Progressive multifocal leucoencephalopathy	Aseptic meningitis/encephalitis Cerebral abscess Space occupying lesion of unknown cause Guillain-Barré Syndrome Transverse myelitis Peripheral neuropathy Dementia Leucoencephalopathy
<b>Dermatology</b>	Kaposi's sarcoma	Severe or recalcitrant seborrhoeic dermatitis Severe or recalcitrant psoriasis Multidermatomal or recurrent herpes zoster
<b>Gastroenterology</b>	Persistent cryptosporidiosis	Oral candidiasis Oral hairy leukoplakia Chronic diarrhoea of unknown cause Weight loss of unknown cause Salmonella, shigella or campylobacter Hepatitis B infection Hepatitis C infection
<b>Oncology</b>	Non-Hodgkin's lymphoma	Anal cancer or anal intraepithelial dysplasia Lung cancer Seminoma Head and neck cancer Hodgkin's lymphoma Castleman's disease
<b>Gynaecology</b>	Cervical cancer	Vaginal intraepithelial neoplasia Cervical intraepithelial neoplasia Grade 2 or above
<b>Haematology</b>		Any unexplained blood dyscrasia including: <ul style="list-style-type: none"> <li>• thrombocytopenia</li> <li>• neutropenia</li> <li>• lymphopenia</li> </ul>
<b>Ophthalmology</b>	Cytomegalovirus retinitis	Infective retinal diseases including herpesviruses and toxoplasma Any unexplained retinopathy
<b>ENT</b>		Lymphadenopathy of unknown cause Chronic parotitis Lymphoepithelial parotid cysts
<b>Other</b>		Mononucleosis-like syndrome (primary HIV infection) Pyrexia of unknown origin Any lymphadenopathy of unknown cause Any sexually transmitted infection

# SECTION 4

**Table: Clinical indicator diseases for paediatric HIV infection**

	<b>AIDS-defining conditions</b>	<b>Other conditions where HIV testing should be considered</b>
<b>ENT</b>		Chronic parotitis, Recurrent and/or troublesome ear infections
<b>Oral</b>		Recurrent oral candidiasis Poor dental hygiene
<b>Respiratory</b>	Pneumocystis CMV pneumonitis Tuberculosis	Recurrent bacterial pneumonia Lymphoid interstitial pneumonitis Bronchiectasis
<b>Neurology</b>	HIV encephalopathy meningitis/encephalitis	Developmental delay Childhood stroke
<b>Dermatology</b>	Kaposi's sarcoma	Severe or recalcitrant dermatitis Multidermatomal or recurrent herpes zoster Recurrent fungal infections Extensive warts or molluscum contagiosum
<b>Gastroenterology</b>	Wasting syndrome Persistent cryptosporidiosis	Unexplained persistent hepatosplenomegaly Hepatitis B infection Hepatitis C infection
<b>Oncology</b>	Lymphoma Kaposi's sarcoma	
<b>Haematology</b>		Any unexplained blood dyscrasia including: <ul style="list-style-type: none"> <li>• thrombocytopenia</li> <li>• neutropenia</li> <li>• lymphopenia</li> </ul>
<b>Ophthalmology</b>	Cytomegalovirus retinitis	Any unexplained retinopathy
<b>Other</b>	Recurrent bacterial infections (eg meningitis, sepsis, osteomyelitis, pneumonia etc.) Pyrexia of unknown origin	

## 4.4 Which test to use?

There are two methods in routine practice for testing for HIV involving either venepuncture and a screening assay where blood is sent to a laboratory for testing or a rapid Point of Care Test (POCT).

### Blood tests

The recommended first line assay is one which tests for HIV antibody AND p24 antigen simultaneously. These are termed fourth generation assays, and have the advantage of reducing the time between infection and testing HIV positive to one month which is one to two weeks earlier than with sensitive third generation (antibody only detection) assays<sup>22</sup>. It is reasonable to expect universal provision of these assays, although they are not offered by all primary screening laboratories.

HIV RNA quantitative assays (viral load tests) are not recommended as screening assays because of the possibility of false positive results, and also the only marginal advantage over fourth generation assays for detecting primary infection.

### Confirmatory assays

Laboratories undertaking screening tests should be able to confirm antibody and antigen/RNA. There is a requirement for three independent assays, able to distinguish HIV-1 from HIV-2. These tests could be provided within the primary testing laboratory, or by a referral laboratory. All new HIV diagnoses should be made following appropriate confirmatory assays and testing a second sample.

Testing including confirmation should follow the standards laid out by the Health Protection Agency<sup>23</sup>.

### Point of care testing (POCT)

Point of care tests offer the advantage of a result from either a fingerprick or mouth swab sample within minutes. They have advantages of ease of use when venepuncture is not possible, eg outside conventional healthcare settings and where a delay in obtaining a result is a disadvantage, but these must be weighed against the disadvantages of a test which has reduced specificity and reduced sensitivity versus current fourth generation lab tests. Due to the low specificity of POCT and therefore the resulting poor positive predictive value all positive results must be confirmed by serological tests as there will be false positives, particularly in lower prevalence environments. Only CE-marked POCT kits should be used and a nominated accredited pathology laboratory should assist with governance issues and quality assurance of the testing process.

POCT is therefore recommended in the following contexts (see BASHH Point of Care Testing Guidance<sup>24</sup>):

1. clinical settings where a rapid turnaround of testing results is desirable
2. community testing sites

3. urgent source testing in cases of exposure incidents
4. circumstances in which venepuncture is refused.

### **General laboratory issues**

All laboratories undertaking any diagnostic HIV services should be able to demonstrate satisfactory external quality control data for the tests undertaken, and should have full accreditation status<sup>23</sup> (such as clinical pathology accreditation (CPA)).

All laboratories must have satisfactory HIV diagnosis confirmatory assay systems available to allow timely definitive diagnoses. This may involve referring samples to specialist virology laboratories, if appropriate, or even national reference laboratories.

All acute healthcare settings should expect to have access to an urgent HIV screening assay result ideally within eight hours, and definitely within 24 hours, to provide optimal support for exposure incidents.

Routine opt-out test results should be expected to be available within 72 hours.

# Pre-test discussion

**The primary purpose of pre-test discussion is to establish informed consent for HIV testing. Lengthy pre-test HIV counselling is not a requirement, unless a patient requests or needs this<sup>1,2,3,4</sup>.**

The essential elements that the pre-test discussion should cover are:

- the benefits of testing to the individual
- details of how the result will be given.

This approach has been successful in GU and antenatal clinics and is generally acceptable.

For some patients raising the issue of HIV testing in other scenarios might require more explanation as to why the doctor or nurse is recommending this, for example when a patient presents with a condition which is more common in HIV infection.

As with any other medical investigation the discussion should address any other issues which may be raised by the patient as it is important that patients are given the opportunity to make a decision with adequate information about the test and the virus.

If a patient refuses a test the reasons why they have made that choice should be explored to ensure that these are not due to incorrect beliefs about the virus or the consequences of testing. If implications for either insurance or criminal prosecution for transmission are raised by the individual as reasons for not testing these should be further explored and any factual inaccuracies corrected (see Appendices 6 and 7).

Some patients may need additional help to make a decision, for example, because English is not their first language. It is essential to ensure that these patients have understood what is proposed, and why. It is also important to establish that the patient understands what a positive and a negative result mean in terms of infection with HIV as some patients could interpret 'positive' as good news.

Children and young people, and those with learning difficulties or mental health problems, may need additional support and time to understand what is proposed and to make a decision (see Appendices 3 and 4).

As with any other investigation the offer of an HIV test should be documented in the patient's case record together with any relevant discussion. If the patient refuses a test the reasons for this should be documented. Usually, written consent is unnecessary and may discourage HIV testing by exceptionalising it.

This advice is consistent with the GMC Guidance *Consent: patients and doctors making decisions together*<sup>25</sup>.



## Post-test discussion

**As with any medical investigation it is essential that clear procedures are established as to how the patient will receive the result, with particular attention paid to the means by which a positive result will be delivered.**

Arrangements for communicating the results should always be discussed and agreed with the patient at the time of testing, particularly if the test is being performed in an outpatient or emergency care setting.

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

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

### **Post-test discussion for individuals who test HIV-negative**

It is considered good practice to offer health promotion screening for sexually transmitted infections and advice around risk reduction or behaviour change including discussion relating to post-exposure prophylaxis (PEP) to those individuals at higher risk of repeat exposure to HIV infection. This is best achieved by onward referral to GUM or HIV services or voluntary sector agencies.

The need for a repeat HIV test if still within the window period after a specific exposure should be discussed. Although fourth generation tests shorten the time from exposure to seroconversion a repeat test at three months is still recommended to definitively exclude HIV infection.

Occasionally HIV results are reported as reactive or equivocal. These patients may be sero-converting (see section on primary HIV infection) and management of re-testing may be complex and so such individuals should be promptly referred to specialist care.

### **Post-test discussion for individuals who test HIV-positive**

As is good clinical practice for any situation where bad news is being conveyed, the result should be given face to face in a confidential environment and in a clear and direct manner. If a patient's first language is not English, consideration should be given to utilisation of an appropriate confidential translation service.

If a positive result is being given by a non-GUM/HIV specialist, it is essential, prior to giving the result, to have clarified knowledge of local specialist services and have established a clear pathway for onward referral.

It is recommended that any individual testing HIV-positive for the first time is seen by a specialist (HIV clinician, specialist nurse or sexual health adviser or voluntary sector counsellor) at the earliest possible opportunity preferably within 48 hours and certainly within two weeks of receiving the result<sup>26</sup>.

More detailed post-test discussion (including assessment of disease stage, consideration of treatment, and partner notification) will be performed by the GUM/HIV specialist team.

### **Non-attendance for positive results**

It is recommended to have an agreed recall process following failure of a patient to return for a positive result as with any other medical condition.

As with all other medical investigations it is the responsibility of the healthcare professional requesting the test to ensure that all results of investigations requested are received and acted upon where necessary.

If there is no means of contacting the patient or if attempts are unsuccessful, it is recommended that advice be sought from the local GUM/HIV team who are likely to have experience and resources to deal with this issue.

# Suspected primary HIV infection

**Primary HIV infection (PHI) or seroconversion illness occurs in approximately 80 per cent of individuals, typically two to four weeks after infection. It is well recognised that this represents a unique opportunity to prevent onward transmission as an individual is considerably more infectious at this stage. Furthermore this may be the only clinical opportunity to detect HIV before advanced immunosuppression many years later.**

It is known that the features of PHI are non-specific, that individuals usually do present to medical services (primary or emergency care) but frequently the diagnosis is missed or not suspected.

The typical symptoms include a combination of any of:

- fever
- rash (maculopapular)
- myalgia
- pharyngitis
- headache/aseptic meningitis.

These resolve spontaneously within two to three weeks and therefore if PHI is suspected, this needs to be investigated at the time of presentation and not deferred.

It is recommended that consideration be given to HIV testing in any person with these symptoms perceived to be at risk of infection. It is acknowledged that in some non-GUM settings details of an individual's sexual risk may be difficult to ascertain, but a low threshold for offering a test should remain.

Although with fourth generation tests infection can be detected much earlier than previously (see section on primary screening assays), in very recent infection – when patients may be most symptomatic – the test may be negative. In this scenario, if PHI is suspected, either urgent referral to specialist services (GU Clinic or HIV service) or a repeat test in seven days is recommended. HIV viral load testing can be used in this clinical setting, but it is recommended that this is only performed with specialist input.

# Appendices

## **Appendix 1. Providing written confirmation of 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.

Clinicians who are not personally acquainted with the patient requesting such a letter should consider referring the patient back to their general practitioner.

If the patient requests a letter confirming their HIV status then ensure that they are correctly identified both at the time blood is taken and when the result is given, by documenting the method of identification such as photographic ID (eg passport, driving licence) in both the notes and the correspondence.

It is preferable to have a written letter signed by the doctor (or another appropriate healthcare professional), rather than a copy of the actual result, and this should be addressed to a specific individual, not 'To whom it may concern'.

## **Appendix 2. Detailed post-test discussion and partner notification**

The following issues would normally be dealt with when the patient is seen at the HIV clinic.

Post-test discussion for individuals who test HIV-positive provides an opportunity to address any immediate concerns and to look at the individual's support and information needs.

It is good practice to check if the patient has any immediate medical problems. In case of any symptoms an immediate link with a doctor or nurse may be indicated.

It is again good practice to offer follow-up appointments (including testing where relevant) and ongoing support for the patient, partner or family where appropriate although this may be done by specialist GUM/HIV services.

Consideration should be given to discussion of partner notification. This will be dependent on the individual but services should have clear guidelines on partner notification in HIV, how it is offered, including offering clients the option of provider referral.

Issues such as preventing the onward transmission of HIV and the medico-legal issues surrounding this, as well as post-exposure prophylaxis for current or future partners who may be at risk, should also be discussed.

### **Appendix 3. Community-based HIV testing**

Historically HIV testing has been performed almost exclusively in medical settings. More recently, programmes have been explored to evaluate testing in community settings. Such programmes acknowledge that many individuals may prefer to test in non-medical settings, may not be registered with primary care, may feel stigmatised by attending medical settings and being targeted for HIV testing, and may not be prepared to disclose risk behaviour, including sexual orientation, to healthcare professionals. The ability to perform community-based testing has been largely enabled by the development of newer technologies for HIV testing, particularly POCT (see section on point of care testing).

Pilot studies have shown that community-based testing is acceptable and feasible and may encourage potentially high-risk individuals who would not otherwise have accessed HIV testing through conventional services<sup>27</sup>. The development of such services, complementary to expansion of existing healthcare based services, should therefore be encouraged and evaluated, particularly in areas where there is a high prevalence of undiagnosed infection. It is vital to ensure that community testing services are linked to the local HIV clinic to ensure that patients will promptly and appropriately access care with clear referral pathways.

Potential disadvantages to community testing include the limitations of the current POCT technologies, such that very recent infection may be missed, and the higher rates of 'false positive' results compared to conventional laboratory-based testing. It is essential that anyone performing HIV testing in a non-healthcare setting has adequate governance arrangements including quality assurance.

The false positive rate will particularly affect individuals whose risk of HIV infection is low, and therefore it is recommended that such programmes are targeted toward communities where undiagnosed HIV prevalence is high, particularly MSM and immigrant communities.

If individuals report high risk activity within the 'window period' of POCTs (currently 12 weeks), either repeat testing in 12 weeks or attendance at a local healthcare HIV testing site should be encouraged.

Individuals who test negative for HIV but who are at risk of other sexually transmitted infections (particularly MSM) should be encouraged to attend local GUM services for testing for other infection and to ensure adequate immunisation against hepatitis viruses.

### **Appendix 4. Testing where the patient lacks capacity to consent (including the unconscious patient)**

Legislation in England, Wales and Scotland provides a framework for decision making on behalf of adults aged 16 and over who lack capacity to make decisions on their own behalf. The Mental Capacity Act 2005

applies to England and Wales. In Scotland the Adults with Incapacity (Scotland) Act 2000 applies, for which there is a separate BMA guidance note. In Northern Ireland common law applies.

A person lacks capacity if, at the time the decision needs to be made, he or she is unable to make a decision because of a mental disorder, or is unable to communicate their decision. Key points to consider when assessing capacity:

1. the assessment of capacity relates to the specific issue in question – in this case consent to HIV testing
2. start from the presumption that the patient has capacity to make this decision
3. consider whether the patient understands what decision they are being asked to make and can weigh up the information relevant to the decision; do they understand the consequences of making a choice?
4. take all possible steps to help patients make a decision for themselves (eg provide information in a more accessible form – drawings, tapes etc). If you judge that a patient lacks capacity to consent to an HIV test you should consider whether this is temporary or permanent. If temporary, you should defer testing until the patient regains capacity, unless testing is immediately necessary to save the patient's life or prevent a serious deterioration of their condition.

If the lack of capacity is, or is likely to be, permanent you should seek a decision from any person with relevant powers of attorney or follow the requirements of any valid advance statements. If the patient has not appointed an attorney nor left a valid advance statement, HIV testing may be undertaken where this is in the best interests of the patient (England and Wales) or is necessary and of benefit to the patient (Scotland).

Guidance on assessing capacity is published by the BMA<sup>28,29,30</sup>. Advice on how to assess appropriate treatment of patients who lack capacity is available in the relevant statutory codes of practice for England<sup>31</sup> and Scotland<sup>32</sup>.

If consciousness is regained the patient should be told of the test result as soon as practicable.

If they die, a decision should be made on disclosure according to the circumstances, eg others at risk and previously disclosed wishes.

## **Appendix 5. Testing infants, children and young people**

Any infant/child/young person thought to be at significant risk of HIV infection, including all those with parents or siblings, who are HIV-infected, should be tested. It is in the best interest of the infant/child/young person to be tested in these circumstances although this only needs to be undertaken urgently in infants who are at risk of rapid disease progression.

## **Who to consider HIV testing**

- infants and children what ever their age where the mother has HIV, or may have died of an HIV-associated condition
- infants born to mothers known to have HIV in pregnancy
- infants born to mothers who have refused an HIV test in pregnancy
- infants and children who are presented for fostering/adoption where there is any risk of blood borne infections<sup>33</sup>
- infants and children newly arrived in the UK from high prevalence areas (they may be unaccompanied minors)
- infants and children with signs and symptoms consistent with an HIV diagnosis
- infants and children being screened for a congenital immunodeficiency
- infants and children in circumstances of post-exposure prophylaxis<sup>34</sup>
- infants and children in cases where there has been sexual abuse (see below).

## **Obtaining consent for HIV testing from children**

In England and Wales, children are defined as those under 18 years old (Children Act 1989) and in Scotland as under 16 (Children (Scotland) Act 1995).

Under English law young people aged 16 years or over are assumed to have the capacity to consent to medical treatment and should be treated in the same way as adults.

Young people under 16 years accessing sexual healthcare (which would include HIV testing as part of a sexual health screen) without a parent or guardian should be assessed for competency to consent<sup>35</sup>.

## **Testing in a non-competent child**

If a child lacks the capacity to consent, then the consent of one parent or carer with parental responsibility is sufficient. If you are aware of parental disagreement, refer to GMC guidance<sup>36</sup>.

## **Refusal of testing by a competent young person**

This is a difficult area and varies according to country in the UK.

In Scotland, parents cannot override a refusal to test by a competent young person.

In England, Wales and Northern Ireland, the law on parents overriding a competent young person's refusal to testing is complex. Legal advice should be sought about whether to apply to the court if testing is thought to be in the best interests of a competent child who refuses.

## **Refusal of testing by parents of a non-competent child or young person**

If parents refuse testing that is clearly in the best interests of a non-competent

child or young person then you should consider involving other members of the multidisciplinary team, an independent advocate or named/designated doctor for child protection before seeking legal advice. This also applies if both a young person with capacity and their parents refuse testing.

### **Testing victims of child sexual abuse**

Testing of victims of child sexual abuse should be considered in every case according to risk factors<sup>36</sup>. Testing should always be performed if post-exposure prophylaxis is to be given. Where parental consent is refused, refer to consent section of RCPCH guidelines on physical signs of child sexual abuse<sup>37</sup>.

### **Testing of children of known HIV-positive parents**

Testing should be offered in all cases at risk of vertical transmission. Increasing evidence shows that children infected vertically can be surviving into teenage years without being diagnosed. Therefore it can not be assumed that older children of mothers with HIV do not require testing. This raises difficult issues of informed consent for these young people, particularly if they are unaware of the mother's diagnosis.

Testing of neonates, children and young people where the mother refuses consent and/or disclosure of her HIV status is a complex area. The overriding consideration must be the best interests of the child, and multidisciplinary decision making and expert advice should be sought, including legal advice where appropriate. A mother's refusal is not acceptable. Referral to a paediatric centre with experience of management of HIV-infected children is strongly recommended.

Parents may need to be supported in making the decision to go ahead to test their children: paediatric HIV support is available nationally through the Children's HIV National Network (CHINN) details of which can be found on the Children's HIV Association (CHIVA) website: [www.chiva.org.uk](http://www.chiva.org.uk).

### **What do children need to know about having an HIV test?**

One of the main reasons that parents do not want to test their children for HIV is because they are afraid to share the diagnosis with them. It should be explained to parents that a developmentally and age appropriate explanation of the test should be given to children and that this does not necessarily mean using the term HIV

1. Older children (usually those older than 11-12 years) should be asked to give consent for an HIV test.
2. Younger children (usually five to ten years of age) can be told they are being tested for a 'bug' in the blood,
3. Pre-school children and infants do not need any formal explanation of why they are having a blood test



## **Appropriate HIV tests for infants and children**

Children older than 18 months of age: HIV antibody test, as for adults.  
Infants younger than 18 months of age: infants born to mothers with HIV receive transplacental maternal HIV antibodies which can usually be detected in the infant blood until about 18 months of age. Infants are therefore tested for genomic evidence of HIV by PCR. For details see BHIVA guidelines on the management of HIV in pregnancy<sup>21</sup>.

## **Appendix 6. The source patient in a needlestick injury or other HIV risk exposure**

The Human Tissue Act (2004) which governs the obtaining of source patient consent supersedes previous GMC guidance.

The source patient's consent to testing must always be gained. Consent from the patient should be obtained from a healthcare worker other than that who sustained the injury. If the rationale for testing is explained, it is unusual for consent to be refused. If the patient does not wish to know the result the option of testing without any documentation should be considered.

For guidance on testing a source patient from a needlestick injury who is unconscious or unable to give consent seek expert advice as the law on this is being reviewed. Guidance on Post-exposure prophylaxis for occupational exposure to HIV is published by the UK CMOs' Expert Advisory Group on AIDS (EAGA)<sup>38</sup>.

## **Appendix 7. HIV testing and insurance**

The ABI code of practice 1994 states that questions regarding whether an individual has ever had an HIV test or a negative result should not be asked. Applicants should however declare any positive results if asked as would be the case with any other medical condition<sup>39,40</sup>.

## **Appendix 8. HIV testing and criminal prosecution for HIV transmission**

Concern about this issue should not be a barrier to testing. There have been a number of prosecutions of individuals under the Offences Against the Person Act 1861 for reckless HIV transmission. This has included a prosecution of an individual who had not been HIV tested. There is detailed guidance on the legal implications of this available from the voluntary sector as well as advice on safer sexual practices designed to minimise risk of transmission of HIV to others<sup>41,42</sup>.

**Appendix 9. Auditable standards**

Standard	Audited by what data and by whom?	How often?	Comments
Offer and uptake of HIV test in GUM	GUMCAD; HPA	Annually	National report; local feedback
Offer and uptake in of HIV test in antenatal care	National Antenatal Infections Screening Monitoring programme (NAISM); HPA	Annually	National report; local feedback
Offer and uptake of HIV test in drug misuse services	Sentinel unlinked anonymous seroprevalence data, HPA	Annually	National report
Offer and uptake of HIV test in TOP services	Local clinic data sources	Annually	National report; local team discussion
Proportion of HIV undiagnosed (by risk group)	Sentinel unlinked anonymous seroprevalence data, HPA	Annually	National report
Proportion of newly diagnosed HIV-positive with CD4 < 200	New diagnoses/SOPHID/CD4 surveillance; HPA	Annually	National report; local feedback
Proportion of newly diagnosed HIV-positive with CD4 < 350	New diagnoses/SOPHID/CD4 surveillance; HPA	Annually	National report; local feedback
Number of HIV tests performed in primary care	Local lab with GUM/HIV/ID input	Annually	Local meeting with PCT if no increase
Number of HIV tests performed in secondary care	Local lab with GUM/HIV/ID input	Annually	Local meeting with relevant teams if no increase
Proportion of individuals with indicator disease being tested for HIV	Local data sources (using IT or case note audits)	Annually	Local team discussion
Offer and uptake of HIV test among TB patients	Chest/ID clinic (using IT or case note audits)	Annually	Joint meeting to discuss
Offer and uptake of HIV test among lymphoma patients	Oncology (using IT or case note audits)	Annually	Joint meeting to discuss
Offer and uptake of HIV test among hepatitis B and C patients	Hepatology/ID/gastroenterology(using IT or case note audits)	Annually	Joint meeting to discuss

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It has not however been possible to accommodate all of the suggestions and advice received as correspondents were divided in their approach to some of the issues. We have therefore made all of the feedback comment to the original consultation draft available on the BHIVA website [www.bhiva.org](http://www.bhiva.org).

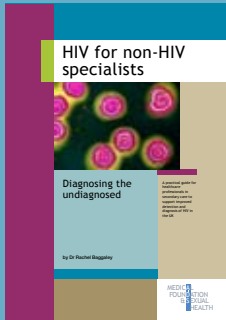
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# HIV for non-HIV specialists

## Diagnosing the undiagnosed

**Over the past decade there have been major advances in the management of HIV which means that those diagnosed early can receive life-saving treatment. However, a third of those with HIV remain undiagnosed, resulting in greater levels of morbidity and mortality.**

### About this booklet

This booklet provides essential information for healthcare professionals in secondary care on:

- the clinical diagnosis of HIV in non-HIV specialist settings, with photographs
- how to offer an HIV test and give results
- barriers to HIV testing for clinicians and patients and strategies for overcoming them
- the background and context of HIV in the UK
- post-exposure prophylaxis and HIV testing where the patient lacks capacity to consent.

PLUS

- new guidelines on HIV testing for use in all healthcare settings, produced by the British Association for Sexual Health and HIV (BASHH), the British HIV Association (BHIVA) and the British Infection Society (BIS).

*HIV for non-HIV specialists* is instructive, practical and easy to use with a detailed contents list, comprehensive index and full colour illustrations.

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# UK National Guidelines for HIV Testing 2008

*prepared jointly by*

British HIV Association

British Association of Sexual Health and HIV

British Infection Society



September 2008

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[www.bhiva.org](http://www.bhiva.org)



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**UK National Guidelines for HIV Testing 2008**

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### Executive summary

- HIV is now a treatable medical condition and the majority of those living with the virus remain fit and well on treatment.
- Despite this a significant number of people in the United Kingdom are unaware of their HIV infection and remain at risk to their own health and of passing their virus unwittingly on to others.
- Late diagnosis is the most important factor associated with HIV-related morbidity and mortality in the UK.
- Patients should therefore be offered and encouraged to accept HIV testing in a wider range of settings than is currently the case.
- Patients with specific indicator conditions should be routinely recommended to have an HIV test.
- All doctors, nurses and midwives should be able to obtain informed consent for an HIV test in the same way that they currently do for any other medical investigation.

## Writing Committee

British Association for Sexual Health and HIV (BASHH)	Adrian Palfreeman
British HIV Association (BHIVA)	Martin Fisher
British Infection Society (BIS)	Ed Ong
College of Emergency Medicine	James Wardrope
Royal College of General Practitioners	Ewen Stewart
Royal College of Nursing	Enrique Castro-Sanchez
Royal College of Physicians	Tim Peto, Karen Rogstad
Royal College of Paediatrics and Child Health	Karen Rogstad
British Medical Association	Julian Sheather
Department of Health Expert Advisory Group on AIDS	Brian Gazzard, Deenan Pillay
General Medical Council	Jane O'Brien
Health Protection Agency	Valerie Delpech
Medical Foundation for AIDS and Sexual Health (MedFASH)	Ruth Lowbury, Russell Fleet
National AIDS Trust	Yusef Azad
Children's HIV Association (CHIVA)	Hermione Lyall
Society of Sexual Health Advisors	James Hardie
UK CAB	Godwin Adegbite
BASHH Clinical Effectiveness Group	Guy Rooney
Lay representative	Richard Whitehead

## Contents

<b>1</b>	Introduction .....	<b>1</b>
<b>2</b>	Background .....	<b>2</b>
<b>3</b>	Confidentiality and HIV testing .....	<b>4</b>
<b>4</b>	Recommendations for testing .....	<b>5</b>
	4.1 Who can test? .....	5
	4.2 Who should be offered a test? .....	5
	4.3 How often to test? .....	6
	4.4 Which test to use? .....	8
<b>5</b>	Pre-test discussion .....	<b>10</b>
<b>6</b>	Post-test discussion .....	<b>11</b>
<b>7</b>	Suspected primary HIV infection .....	<b>13</b>
	Appendix 1: <i>Providing written confirmation of results</i> .....	<b>14</b>
	Appendix 2: <i>Detailed post-test discussion and partner notification</i> .....	<b>14</b>
	Appendix 3: <i>Community-based HIV testing</i> .....	<b>14</b>
	Appendix 4: <i>Testing where the patient lacks capacity to consent</i> .....	<b>15</b>
	Appendix 5: <i>Testing infants, children and young people</i> .....	<b>16</b>
	Appendix 6: <i>The source patient in a needlestick injury or other HIV risk exposure</i> .....	<b>18</b>
	Appendix 7: <i>HIV testing and insurance</i> .....	<b>18</b>
	Appendix 8: <i>HIV testing and criminal prosecution for HIV transmission</i> ...	<b>18</b>
	Appendix 9: <i>Auditable standards</i> .....	<b>19</b>
	Acknowledgements .....	<b>20</b>
	References .....	<b>21</b>



# 1

## Introduction

These guidelines are intended to facilitate an increase in HIV testing in all healthcare settings as recommended by the UK's Chief Medical Officers and Chief Nursing Officers [1–4] in order to reduce the proportion of individuals with undiagnosed HIV infection, with the aim of benefiting both individual and public health. Misconceptions remain regarding HIV testing that hinder increased testing. In particular, many clinicians believe that lengthy pre-test counselling is required prior to testing. These guidelines provide the information needed to enable any clinician to perform an HIV test within good clinical practice and encourage 'normalisation' of HIV testing.

For this change in approach to be beneficial and ethically acceptable, it is imperative that following a positive HIV diagnosis, a newly diagnosed individual is immediately linked into appropriate HIV treatment and care.

This guidance refers to both diagnostic testing of individuals presenting with 'clinical indicator diseases' (i.e. where HIV infection enters the differential diagnosis) and opportunistic screening of populations where this is indicated on the basis of prevalence data. We also include an appendix on the provision of community-based HIV testing (Appendix 3).

It must be emphasised that in the UK, HIV testing remains voluntary and confidential. This is entirely possible within any healthcare setting if these guidelines are followed.

## 2

## Background

Whilst the availability of highly active antiretroviral therapy (HAART) has transformed the outcome for individuals with HIV infection, there continues to be significant and avoidable morbidity and mortality relating to HIV infection in the UK. A national audit by the British HIV Association (BHIVA) showed that of deaths occurring amongst HIV-positive adults in the UK in 2006, 24 per cent were directly attributable to the diagnosis of HIV being made too late for effective treatment [5]. Furthermore, it has been shown that many of these 'late presenters' have been seen in the recent past by healthcare professionals without the diagnosis having been made [6]. National surveillance data shows that approximately one-third of all HIV infections in adults in the UK remain undiagnosed [7] and that approximately 25 per cent of newly diagnosed individuals have a CD4 cell count of less than 200 (an accepted marker of 'late' diagnosis).

Late diagnosis of HIV infection has been associated with increased mortality and morbidity [7], impaired response to HAART [8] and increased cost to healthcare services [9]. Furthermore, from a public health perspective, knowledge of HIV status is associated with a reduction in risk behaviour [10] and therefore it is anticipated that earlier diagnosis will result in reduced onward transmission [11]. Modelling has suggested that over 50 per cent of new infections in the US occur through transmission from individuals in whom HIV has not been diagnosed. Furthermore, modelling in the US has also suggested that routine screening for HIV infection is cost effective and comparable to costs of other routinely offered screening where the prevalence of HIV exceeds 0.05 per cent [12].

All the published literature suggests that uptake of testing is increased where universal routine ('opt-out') strategies have been adopted [13–15].

Universal HIV ('opt-out') testing means that all individuals attending specified settings are offered and recommended an HIV test as part of routine care but an individual has the option to refuse a test.

Prior to 2001, HIV testing was largely confined to individuals presenting and requesting HIV testing in GUM clinics. The uptake of testing was low and a significant proportion of HIV-positive individuals were known to remain undiagnosed. The National Strategy for Sexual Health and HIV (2001) [16] recommended that all attendees at GUM clinics should be offered an HIV test with clear targets for the proportion offered testing and test uptake. Since this policy was introduced the proportion of infections which remain undiagnosed has reduced but still remains significant [25% in heterosexuals, 47% in men who have sex with men (MSM)] [7]. The majority of GUM clinics now utilise a universal 'opt-out' approach to testing with high acceptability and success although the reasons why some high-risk individuals still refuse testing require further study.

In the antenatal setting, prior to 2000, uptake of HIV testing was highly variable and dependent upon healthcare worker factors rather than clinical need.

The only randomised controlled trial published to date [13] on testing methods showed that a universal 'opt-out' approach to HIV testing in antenatal patients was acceptable, did not cause anxiety and had a higher uptake than other methods. Assessing patients for risk merely reduced the number of patients tested and it is recognised that women who refuse antenatal testing are more likely to be HIV positive.

The adoption of universal opt-out testing [17] has resulted in a dramatic improvement in antenatal testing rates and a significant reduction in the proportion of HIV infections that remain undiagnosed prior to delivery, from 18 per cent in 2000 to fewer than 10 per cent in 2006 [7]. Furthermore the median CD4 cell count at HIV diagnosis of women detected through antenatal screening has been consistently higher than among other women (even after adjusting for age) and heterosexual men diagnosed with HIV. This indicates that efforts to detect HIV infection in asymptomatic individuals are likely to result in earlier diagnosis, hence reducing morbidity and mortality in diagnosed individuals as well as reducing onward transmission [7].



In the USA in 2006 the Centers for Disease Control and Prevention (CDC) recommended opt-out testing for all individuals aged 13 to 64 presenting to any healthcare facility (mainly Emergency Rooms) for any reason [18]. Initial reports suggest that this has been successful in increasing the number of new HIV diagnoses but barriers continue to exist including legal requirements in some states regarding testing, a requirement for written consent, and lack of access for some patients to ongoing HIV treatment and care [19].

In the UK, where the vast majority of patients have access to healthcare free at the point of delivery, all patients have access to a general practitioner, and where there are pressures upon Emergency Departments to achieve four-hour waiting targets, we believe universal opt-out testing in all settings may not be the most feasible approach but support the use of opt-out testing in certain situations.

# 3

## Confidentiality and HIV testing

HIV testing has historically been exceptionalised and treated differently to testing for other serious medical conditions. The outlook for individuals testing positive for HIV is now better than for many other serious illnesses for which clinicians routinely test. Whilst there remains stigma associated with HIV infection, this can be minimised by following the general principles of confidentiality for any medical condition as laid down by the GMC in its guidance *Confidentiality: protecting and providing information* [20].

*'Patients have a right to expect that information about them will be held in confidence by their doctors. Confidentiality is central to trust between doctors and patients. Without assurances about confidentiality, patients may be reluctant to give doctors the information they need in order to provide good care.'*

The result of an HIV test (if positive) should be given directly by the testing clinician (or team) to the patient and not via any third party, including relatives or other clinical teams unless the patient has specifically agreed to this (see section on post-test discussion).

# 4

## Recommendations for testing

### 4.1 Who can test?

It should be within the competence of any doctor, midwife, nurse or trained healthcare worker to obtain consent for and conduct an HIV test.

### 4.2 Who should be offered a test?

**A. Universal HIV testing is recommended in all of the following settings:**

1. GUM or sexual health clinics
2. antenatal services
3. termination of pregnancy services
4. drug dependency programmes
5. healthcare services for those diagnosed with tuberculosis, hepatitis B, hepatitis C and lymphoma.

**B. An HIV test should be considered in the following settings where diagnosed HIV prevalence in the local population (PCT/LA) exceeds 2 in 1000 population (see local PCT data<sup>†</sup>):**

1. all men and women registering in general practice
2. all general medical admissions.

The introduction of universal HIV testing in these settings should be thoroughly evaluated for acceptability and feasibility and the resultant data made available to better inform the ongoing implementation of these guidelines.

**C. HIV testing should be also routinely offered and recommended to the following patients:**

1. all patients presenting for healthcare where HIV, including primary HIV infection, enters the differential diagnosis (see table of indicator diseases and section on primary HIV infection)
2. all patients diagnosed with a sexually transmitted infection
3. all sexual partners of men and women known to be HIV positive
4. all men who have disclosed sexual contact with other men
5. all female sexual contacts of men who have sex with men
6. all patients reporting a history of injecting drug use
7. all men and women known to be from a country of high HIV prevalence (>1%\*)
8. all men and women who report sexual contact abroad or in the UK with individuals from countries of high HIV prevalence.\*

\* for an up to date list see

<http://www.unaids.org/en/KnowledgeCentre/HIVData/Epidemiology/latestEpiData.asp>

<sup>†</sup> Diagnosed prevalence is a good indicator of the undiagnosed prevalence in a population (ratio 2:1). All PCTs are routinely informed of the diagnosed prevalence rate by the Health Protection Agency (HPA) Survey of Prevalent HIV Diagnoses (SOPHID) data on an annual basis (further information on SOPHID data and its dissemination is available at [http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb\\_C/1201767906579](http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1201767906579)). A diagnosed prevalence exceeding 2 in 1000, in those aged between 15 and 59, is a proxy for an undiagnosed prevalence exceeding 1 in 1000, the threshold at which routine testing is assumed to be cost effective based on the US data [18].

*D. HIV testing should also be routinely performed in the following groups in accordance with existing Department of Health guidance:*

1. blood donors
2. dialysis patients
3. organ transplant donors and recipients.

### 4.3. How often to test?

Repeat testing should be provided for the following groups:

1. all individuals who have tested HIV negative but where a possible exposure has occurred within the window period
2. men who have sex with men (MSM) – annually or more frequently if clinical symptoms are suggestive of seroconversion or ongoing high risk exposure
3. injecting drug users – annually or more frequently if clinical symptoms are suggestive of seroconversion (see section on primary HIV infection)
4. antenatal care – women who refuse an HIV test at booking should be re-offered a test, and should they decline again a third offer of a test should be made at 36 weeks. Women presenting to services for the first time in labour should be offered a point of care test (POCT).

A POCT test may also be considered for the infant of a woman who refuses testing antenatally.

In areas of higher seroprevalence, or where there are other risk factors, women who are HIV negative at booking may be offered a routine second test at 34–36 weeks' gestation as recommended in the BHIVA pregnancy guidelines [21].

**Table 1: Clinical indicator diseases for adult HIV infection**

	AIDS-defining conditions	Other conditions where HIV testing should be offered
Respiratory	Tuberculosis Pneumocystis	Bacterial pneumonia Aspergillosis
Neurology	Cerebral toxoplasmosis Primary cerebral lymphoma Cryptococcal meningitis Progressive multifocal leucoencephalopathy	Aseptic meningitis/encephalitis Cerebral abscess Space occupying lesion of unknown cause Guillain–Barré syndrome Transverse myelitis Peripheral neuropathy Dementia Leucoencephalopathy
Dermatology	Kaposi's sarcoma	Severe or recalcitrant seborrhoeic dermatitis Severe or recalcitrant psoriasis Multidermatomal or recurrent herpes zoster
Gastroenterology	Persistent cryptosporidiosis	Oral candidiasis Oral hairy leukoplakia Chronic diarrhoea of unknown cause Weight loss of unknown cause Salmonella, shigella or campylobacter Hepatitis B infection Hepatitis C infection
Oncology	Non-Hodgkin's lymphoma	Anal cancer or anal intraepithelial dysplasia Lung cancer Seminoma Head and neck cancer Hodgkin's lymphoma Castleman's disease
Gynaecology	Cervical cancer	Vaginal intraepithelial neoplasia Cervical intraepithelial neoplasia Grade 2 or above
Haematology		Any unexplained blood dyscrasia including: <ul style="list-style-type: none"> <li>• thrombocytopenia</li> <li>• neutropenia</li> <li>• lymphopenia</li> </ul>
Ophthalmology	Cytomegalovirus retinitis	Infective retinal diseases including herpesviruses and toxoplasma Any unexplained retinopathy
ENT		Lymphadenopathy of unknown cause Chronic parotitis Lymphoepithelial parotid cysts
Other		Mononucleosis-like syndrome (primary HIV infection) Pyrexia of unknown origin Any lymphadenopathy of unknown cause Any sexually transmitted infection

**Table 2: Clinical indicator diseases for paediatric HIV infection**

	AIDS-defining conditions	Other conditions where HIV testing should be considered
ENT		Chronic parotitis Recurrent and/or troublesome ear infections
Oral		Recurrent oral candidiasis Poor dental hygiene
Respiratory	Pneumocystis CMV pneumonitis Tuberculosis	Recurrent bacterial pneumonia Lymphoid interstitial pneumonitis Bronchiectasis
Neurology	HIV encephalopathy meningitis/encephalitis	Developmental delay Childhood stroke
Dermatology	Kaposi's sarcoma	Severe or recalcitrant dermatitis Multidermatomal or recurrent herpes zoster Recurrent fungal infections Extensive warts or molluscum contagiosum
Gastroenterology	Wasting syndrome Persistent cryptosporidiosis	Unexplained persistent hepatosplenomegaly Hepatitis B infection Hepatitis C infection
Oncology	Lymphoma Kaposi's sarcoma	
Haematology		Any unexplained blood dyscrasia including: <ul style="list-style-type: none"> <li>• thrombocytopenia</li> <li>• neutropenia</li> <li>• lymphopenia</li> </ul>
Ophthalmology	Cytomegalovirus retinitis	Any unexplained retinopathy
Other	Recurrent bacterial infections (e.g. meningitis, sepsis, osteomyelitis, pneumonia etc.) Pyrexia of unknown origin	

#### 4.4 Which test to use?

There are two methods in routine practice for testing for HIV involving either venepuncture and a screening assay where blood is sent to a laboratory for testing or a rapid point of care test (POCT).

##### Blood tests

The recommended first-line assay is one which tests for HIV antibody AND p24 antigen simultaneously. These are termed fourth generation assays, and have the advantage of reducing the time between infection and testing HIV positive to one month which is one to two weeks earlier than with sensitive third generation (antibody only detection) assays [22]. It is reasonable to expect universal provision of these assays, although they are not offered by all primary screening laboratories.

HIV RNA quantitative assays (viral load tests) are not recommended as screening assays because of the possibility of false positive results, and also only marginal advantage over fourth generation assays for detecting primary infection.

### **Confirmatory assays**

Laboratories undertaking screening tests should be able to confirm antibody and antigen/RNA. There is a requirement for three independent assays, able to distinguish HIV-1 from HIV-2. These tests could be provided within the primary testing laboratory, or by a referral laboratory. All new HIV diagnoses should be made following appropriate confirmatory assays and testing a second sample.

Testing including confirmation should follow the standards laid out by the Health Protection Agency [23].

### ***Point of care testing (POCT)***

Point of care tests offer the advantage of a result from either a fingerprick or mouth swab sample within minutes. They have advantages of ease of use when venepuncture is not possible, e.g. outside conventional healthcare settings and where a delay in obtaining a result is a disadvantage, but these must be weighed against the disadvantages of a test which has reduced specificity and reduced sensitivity versus current fourth generation laboratory tests. Due to the low specificity of POCT and therefore the resulting poor positive predictive value all positive results must be confirmed by serological tests as there will be false positives, particularly in lower prevalence environments. Only CE-marked POCT kits should be used and a nominated accredited pathology laboratory should assist with governance issues and quality assurance of the testing process.

POCT is therefore recommended in the following contexts (see BASHH Point of Care Testing Guidance) [24]:

1. clinical settings where a rapid turnaround of testing results is desirable
2. community testing sites
3. urgent source testing in cases of exposure incidents
4. circumstances in which venepuncture is refused.

### ***General laboratory issues***

All laboratories undertaking any diagnostic HIV services should be able to demonstrate satisfactory external quality control data for the tests undertaken, and should have full accreditation status [23] [such as clinical pathology accreditation (CPA)].

All laboratories must have satisfactory HIV diagnosis confirmatory assay systems available to allow timely definitive diagnoses. This may involve referring samples to specialist virology laboratories, if appropriate, or even national reference laboratories.

All acute healthcare settings should expect to have access to an urgent HIV screening assay result ideally within eight hours, and definitely within 24 hours, to provide optimal support for exposure incidents.

Routine opt-out test results should be expected to be available within 72 hours.

## 5

## Pre-test discussion

The primary purpose of pre-test discussion is to establish informed consent for HIV testing. Lengthy pre-test HIV counselling is not a requirement, unless a patient requests or needs this [1–4].

The essential elements that the pre-test discussion should cover are:

- the benefits of testing to the individual
- details of how the result will be given.

This approach has been successful in GU and antenatal clinics and is generally acceptable.

For some patients raising the issue of HIV testing in other scenarios might require more explanation as to why the doctor or nurse is recommending this, for example when a patient presents with a condition which is more common in HIV infection.

As with any other medical investigation the discussion should address any other issues which may be raised by the patient as it is important that patients are given the opportunity to make a decision with adequate information about the test and the virus.

If a patient refuses a test the reasons why they have made that choice should be explored to ensure that these are not due to incorrect beliefs about the virus or the consequences of testing. If implications for either insurance or criminal prosecution for transmission are raised by the individual as reasons for not testing these should be further explored and any factual inaccuracies corrected (see Appendices 6 and 7).

Some patients may need additional help to make a decision, for example, because English is not their first language. It is essential to ensure that these patients have understood what is proposed, and why. It is also important to establish that the patient understands what a positive and a negative result mean in terms of infection with HIV as some patients could interpret 'positive' as good news.

Children and young people, and those with learning difficulties or mental health problems, may need additional support and time to understand what is proposed and to make a decision (see Appendices 3 and 4).

As with any other investigation the offer of an HIV test should be documented in the patient's case record together with any relevant discussion. If the patient refuses a test the reasons for this should be documented. Usually, written consent is unnecessary and may discourage HIV testing by exceptionalising it.

This advice is consistent with the GMC Guidance *Consent: patients and doctors making decisions together* [25].



# 6

## Post-test discussion

As with any medical investigation it is essential that clear procedures are established as to how the patient will receive the result, with particular attention paid to the means by which a positive result will be delivered.

Arrangements for communicating the results should always be discussed and agreed with the patient at the time of testing, particularly if the test is being performed in an outpatient or emergency care setting.

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

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

### Post-test discussion for individuals who test HIV negative

It is considered good practice to offer health promotion screening for sexually transmitted infections and advice around risk reduction or behaviour change including discussion relating to post-exposure prophylaxis (PEP) to those individuals at higher risk of repeat exposure to HIV infection. This is best achieved by onward referral to GUM or HIV services or voluntary sector agencies.

The need for a repeat HIV test if still within the window period after a specific exposure should be discussed. Although fourth generation tests shorten the time from exposure to seroconversion a repeat test at three months is still recommended to definitively exclude HIV infection.

Occasionally HIV results are reported as reactive or equivocal. These patients may be seroconverting (see section on primary HIV infection) and management of re-testing may be complex and so such individuals should be promptly referred to specialist care.

### Post-test discussion for individuals who test HIV positive

As is good clinical practice for any situation where bad news is being conveyed, the result should be given face to face in a confidential environment and in a clear and direct manner. If a patient's first language is not English, consideration should be given to utilisation of an appropriate confidential translation service.

If a positive result is being given by a non-GUM/HIV specialist, it is essential, prior to giving the result, to have clarified knowledge of local specialist services and have established a clear pathway for onward referral.

It is recommended that any individual testing HIV positive for the first time is seen by a specialist (HIV clinician, specialist nurse or sexual health advisor or voluntary sector counsellor) at the earliest possible opportunity, preferably within 48 hours and certainly within two weeks of receiving the result [26].

More detailed post-test discussion (including assessment of disease stage, consideration of treatment, and partner notification) will be performed by the GUM/HIV specialist team.

### **Non-attendance for positive results**

It is recommended to have an agreed recall process following failure of a patient to return for a positive result as with any other medical condition.

As with all other medical investigations it is the responsibility of the healthcare professional requesting the test to ensure that all results of investigations requested are received and acted upon where necessary.

If there is no means of contacting the patient or if attempts are unsuccessful, it is recommended that advice be sought from the local GUM/HIV team who are likely to have experience and resources to deal with this issue.

## 7

## Suspected primary HIV infection

Primary HIV infection (PHI) or seroconversion illness occurs in approximately 80 per cent of individuals, typically two-to-four weeks after infection. It is well recognised that this represents a unique opportunity to prevent onward transmission as an individual is considerably more infectious at this stage. Furthermore this may be the only clinical opportunity to detect HIV before advanced immunosuppression many years later.

It is known that the features of PHI are non-specific, that individuals usually do present to medical services (primary or emergency care) but frequently the diagnosis is missed or not suspected.

The typical symptoms include a combination of any of:

- fever
- rash (maculopapular)
- myalgia
- pharyngitis
- headache/aseptic meningitis.

These resolve spontaneously within two-to-three weeks and therefore if PHI is suspected, this needs to be investigated at the time of presentation and not deferred.

It is recommended that consideration be given to HIV testing in any person with these symptoms perceived to be at risk of infection. It is acknowledged that in some non-GUM settings details of an individual's sexual risk may be difficult to ascertain, but a low threshold for offering a test should remain.

Although with fourth generation tests infection can be detected much earlier than previously (see section on primary screening assays), in very recent infection – when patients may be most symptomatic – the test may be negative. In this scenario, if PHI is suspected, either urgent referral to specialist services (GU clinic or HIV service) or a repeat test in seven days is recommended. HIV viral load testing can be used in this clinical setting, but it is recommended that this is only performed with specialist input.

## Appendices

### *Appendix 1: Providing written confirmation of 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.

Clinicians who are not personally acquainted with the patient requesting such a letter should consider referring the patient back to their general practitioner.

If the patient requests a letter confirming their HIV status then ensure that they are correctly identified both at the time blood is taken and when the result is given, by documenting the method of identification such as photographic ID (e.g. passport, driving licence) in both the notes and the correspondence.

It is preferable to have a written letter signed by the doctor (or another appropriate healthcare professional), rather than a copy of the actual result, and this should be addressed to a specific individual, not 'To whom it may concern'.

### *Appendix 2: Detailed post-test discussion and partner notification*

The following issues would normally be dealt with when the patient is seen at the HIV clinic.

Post-test discussion for individuals who test HIV positive provides an opportunity to address any immediate concerns and to look at the individual's support and information needs.

It is good practice to check if the patient has any immediate medical problems. In case of any symptoms an immediate link with a doctor or nurse may be indicated.

It is again good practice to offer follow-up appointments (including testing where relevant) and ongoing support for the patient, partner or family where appropriate, although this may be done by specialist GUM/HIV services.

Consideration should be given to discussion of partner notification. This will be dependent on the individual but services should have clear guidelines on partner notification in HIV, how it is offered, including offering clients the option of provider referral.

Issues such as preventing the onward transmission of HIV and the medico-legal issues surrounding this, as well as post-exposure prophylaxis for current or future partners who may be at risk, should also be discussed.

### *Appendix 3: Community-based HIV testing*

Historically, HIV testing has been performed almost exclusively in medical settings. More recently, programmes have been explored to evaluate testing in community settings. Such programmes acknowledge that many individuals may prefer to test in non-medical settings, may not be registered with primary care, may feel stigmatised by attending medical settings and being targeted for HIV testing, and may not be prepared to disclose risk behaviour, including sexual orientation, to healthcare professionals. The ability to perform community-based testing has been largely enabled by the development of newer technologies for HIV testing, particularly POCT (see section on point of care testing).

Pilot studies have shown that community-based testing is acceptable and feasible and may encourage potentially high-risk individuals who would not otherwise have accessed HIV testing through conventional services [27]. The development of such services, complementary to expansion of existing healthcare-based services, should therefore be encouraged and evaluated, particularly in areas where there is a high prevalence of undiagnosed infection. It is vital to ensure that community testing services are linked to the local HIV clinic to ensure that patients will promptly and appropriately access care with clear referral pathways.

Potential disadvantages to community testing include the limitations of the current POCT technologies, such that very recent infection may be missed, and the higher rates of 'false positive' results compared to conventional laboratory-based testing. It is essential that anyone performing HIV testing in a non-healthcare setting has adequate governance arrangements including quality assurance.

The false positive rate will particularly affect individuals whose risk of HIV infection is low, and therefore it is recommended that such programmes are targeted toward communities where undiagnosed HIV prevalence is high, particularly MSM and immigrant communities.

If individuals report high-risk activity within the 'window period' of POCTs (currently 12 weeks), either repeat testing in 12 weeks or attendance at a local healthcare HIV testing site should be encouraged.

Individuals who test negative for HIV but who are at risk of other sexually transmitted infections (particularly MSM) should be encouraged to attend local GUM services for testing for other infection and to ensure adequate immunisation against hepatitis viruses.

### *Appendix 4: Testing where the patient lacks capacity to consent (including the unconscious patient)*

Legislation in England, Wales and Scotland provides a framework for decision-making on behalf of adults aged 16 and over who lack capacity to make decisions on their own behalf. The Mental Capacity Act 2005 applies to England and Wales. In Scotland the Adults with Incapacity (Scotland) Act 2000 applies, for which there is a separate BMA guidance note. In Northern Ireland common law applies.

A person lacks capacity if, at the time the decision needs to be made, he or she is unable to make a decision because of a mental disorder, or is unable to communicate their decision. Key points to consider when assessing capacity:

1. The assessment of capacity relates to the specific issue in question – in this case consent to HIV testing.
2. Start from the presumption that the patient has capacity to make this decision.
3. Consider whether the patient understands what decision they are being asked to make and can weigh up the information relevant to the decision; do they understand the consequences of making a choice?
4. Take all possible steps to help patients make a decision for themselves (e.g. provide information in a more accessible form – drawings, tapes etc.). If you judge that a patient lacks capacity to consent to an HIV test you should consider whether this is temporary or permanent. If temporary, you should defer testing until the patient regains capacity, unless testing is immediately necessary to save the patient's life or prevent a serious deterioration of their condition.

If the lack of capacity is, or is likely to be, permanent you should seek a decision from any person with relevant powers of attorney or follow the requirements of any valid advance statements. If the patient has not appointed an attorney nor left a valid advance statement, HIV testing may be undertaken where this is in the best interests of the patient (England and Wales) or is necessary and of benefit to the patient (Scotland).

Guidance on assessing capacity is published by the BMA [28–30]. Advice on how to assess appropriate treatment of patients who lack capacity is available in the relevant statutory codes of practice for England [31] and Scotland [32].

If consciousness is regained the patient should be told of the test result as soon as practicable.

If they die, a decision should be made on disclosure according to the circumstances, e.g. others at risk and previously disclosed wishes.

### *Appendix 5: Testing infants, children and young people*

Any infant/child/young person thought to be at significant risk of HIV infection, including all those with parents or siblings who are HIV-infected, should be tested. It is in the best interest of the infant/child/young person to be tested in these circumstances although this only needs to be undertaken urgently in infants who are at risk of rapid disease progression.

#### ***Who to consider for HIV testing***

- infants and children whatever their age where the mother has HIV, or may have died of an HIV-associated condition
- infants born to mothers known to have HIV in pregnancy
- infants born to mothers who have refused an HIV test in pregnancy
- infants and children who are presented for fostering/adoption where there is any risk of blood-borne infections [33]
- infants and children newly arrived in the UK from high-prevalence areas (they may be unaccompanied minors)
- infants and children with signs and symptoms consistent with an HIV diagnosis
- infants and children being screened for a congenital immunodeficiency
- infants and children in circumstances of post-exposure prophylaxis [34]
- infants and children in cases where there has been sexual abuse (see below).

#### ***Obtaining consent for HIV testing from children***

In England and Wales, children are defined as those under 18 years old (Children Act 1989) and in Scotland as under 16 [Children (Scotland) Act 1995].

Under English law young people aged 16 years or over are assumed to have the capacity to consent to medical treatment and should be treated in the same way as adults.

Young people under 16 years accessing sexual healthcare (which would include HIV testing as part of a sexual health screen) without a parent or guardian should be assessed for competency to consent [35].

#### ***Testing in a non-competent child***

If a child lacks the capacity to consent, then the consent of one parent or carer with parental responsibility is sufficient. If you are aware of parental disagreement, refer to GMC guidance [36].

#### ***Refusal of testing by a competent young person***

This is a difficult area and varies according to country in the UK.

In Scotland, parents cannot override a refusal to test by a competent young person.

In England, Wales and Northern Ireland, the law on parents overriding a competent young person's refusal to testing is complex. Legal advice should be sought about whether to apply to the court if testing is thought to be in the best interests of a competent child who refuses.

### ***Refusal of testing by parents of a non-competent child or young person***

If parents refuse testing that is clearly in the best interests of a non-competent child or young person then you should consider involving other members of the multidisciplinary team, an independent advocate or named/designated doctor for child protection before seeking legal advice. This also applies if both a young person with capacity and their parents refuse testing.

### ***Testing victims of child sexual abuse***

Testing of victims of child sexual abuse should be considered in every case according to risk factors [36]. Testing should always be performed if post-exposure prophylaxis is to be given. Where parental consent is refused, refer to consent section of RCPCH guidelines on physical signs of child sexual abuse [37].

### ***Testing of children of known HIV-positive parents***

Testing should be offered in all cases at risk of vertical transmission. Increasing evidence shows that children infected vertically can survive into teenage years without being diagnosed. Therefore, it can not be assumed that older children of mothers with HIV do not require testing. This raises difficult issues of informed consent for these young people, particularly if they are unaware of the mother's diagnosis.

Testing of neonates, children and young people where the mother refuses consent and/or disclosure of her HIV status is a complex area. The overriding consideration must be the best interests of the child, and multidisciplinary decision-making and expert advice should be sought, including legal advice where appropriate. It is not acceptable to simply accept a mother's refusal. Referral to a paediatric centre with experience of management of HIV-infected children is strongly recommended.

Parents may need to be supported in making the decision to go ahead to test their children; paediatric HIV support is available nationally through the Children's HIV National Network (CHINN), details of which can be found on the Children's HIV Association (CHIVA) website, [www.chiva.org.uk](http://www.chiva.org.uk).

### ***What do children need to know about having an HIV test?***

One of the main reasons that parents do not want to test their children for HIV is because they are afraid to share the diagnosis with them. It should be explained to parents that a developmentally and age-appropriate explanation of the test should be given to children and that this does not necessarily mean using the term HIV.

- 1) Older children (usually those older than 11) should be asked to give consent for an HIV test.
- 2) Younger children (usually five to ten years of age) can be told they are being tested for a 'bug' in the blood.
- 3) Pre-school children and infants do not need any formal explanation of why they are having a blood test.

### ***Appropriate HIV tests for infants and children***

Children older than 18 months of age: HIV antibody test, as for adults.

Infants younger than 18 months of age: infants born to mothers with HIV receive transplacental maternal HIV antibodies which can usually be detected in the infant blood until about 18 months of age. Infants are therefore tested for genomic evidence of HIV by PCR. For details see BHIVA guidelines on the management of HIV in pregnancy [21].

### *Appendix 6: The source patient in a needlestick injury or other HIV risk exposure*

The Human Tissue Act (2004) which governs the obtaining of source patient consent supersedes previous GMC guidance.

The source patient's consent to testing must always be gained. Consent from the patient should be obtained from a healthcare worker other than that who sustained the injury. If the rationale for testing is explained, it is unusual for consent to be refused. If the patient does not wish to know the result the option of testing without any documentation should be considered.

For guidance on testing a source patient from a needlestick injury who is unconscious or unable to give consent seek expert advice as the law on this is being reviewed. Guidance on post-exposure prophylaxis for occupational exposure to HIV is published by the UK CMOs' Expert Advisory Group on AIDS (EAGA) [38].

### *Appendix 7: HIV testing and insurance*

The ABI code of practice 1994 states that questions regarding whether an individual has ever had an HIV test or a negative result should not be asked. Applicants should however declare any positive results if asked as would be the case with any other medical condition [39,40].

### *Appendix 8: HIV testing and criminal prosecution for HIV transmission*

Concern about this issue should not be a barrier to testing. There have been a number of prosecutions of individuals under the Offences Against the Person Act 1861 for reckless HIV transmission. This has included a prosecution of an individual who had not been HIV tested. There is detailed guidance on the legal implications of this available from the voluntary sector as well as advice on safer sexual practices designed to minimise risk of transmission of HIV to others [41,42].



## Appendix 9: Auditable standards

Standard	Audited by what data and by whom?	How often?	Comments
Offer and uptake of HIV test in GUM	GUMCAD; HPA	Annually	National report; local feedback
Offer and uptake in of HIV test in antenatal care	National Antenatal Infections Screening Monitoring programme (NAISM); HPA	Annually	National report; local feedback
Offer and uptake of HIV test in drug misuse services	Sentinel unlinked anonymous seroprevalence data, HPA	Annually	National report
Offer and uptake of HIV test in TOP services	Local clinic data sources	Annually	National report; local team discussion
Proportion of HIV undiagnosed (by risk group)	Sentinel unlinked anonymous seroprevalence data, HPA	Annually	National report
Proportion of newly diagnosed HIV positive with CD4 < 200	New diagnoses/SOPHID/CD4 surveillance; HPA	Annually	National report; local feedback
Proportion of newly diagnosed HIV positive with CD4 < 350	New diagnoses/SOPHID/CD4 surveillance; HPA	Annually	National report; local feedback
Number of HIV tests performed in primary care	Local lab with GUM/HIV/ID input	Annually	Local meeting with PCT if no increase
Number of HIV tests performed in secondary care	Local lab with GUM/HIV/ID input	Annually	Local meeting with relevant teams if no increase
Proportion of individuals with indicator disease being tested for HIV	Local data sources (using IT or case note audits)	Annually	Local team discussion
Offer and uptake of HIV test among TB patients	Chest/ID clinic (using IT or case note audits)	Annually	Joint meeting to discuss
Offer and uptake of HIV test among lymphoma patients	Oncology (using IT or case note audits)	Annually	Joint meeting to discuss
Offer and uptake of HIV test among hepatitis B and C patients	Hepatology/ID/gastroenterology (using IT or case note audits)	Annually	Joint meeting to discuss

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# UK National Guidelines for HIV Testing 2008