
HIV POST-EXPOSURE PROPHYLAXIS

Guidance from the UK Chief Medical Officers'

Expert Advisory Group on AIDS

Revised: February 2004

Implementing
Getting Ahead of the Curve:
action on blood-borne viruses

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CHAPTER 1

INTRODUCTION

1.1 Background

1. This document updates guidance on occupational HIV post-exposure prophylaxis (PEP) from the UK Chief Medical Officers' Expert Advisory Group on AIDS (EAGA) issued in July 2000 [1].
2. The most substantial addition to the guidance is a new annex, Annex G, on PEP for patients following possible exposure to an infected health care worker. This issue was not addressed in the previous guidance and recognises a need for equity in management of blood exposure incidents in the health care setting. It also serves as a reminder of the responsibilities of health care workers to seek and follow confidential advice on whether they should be tested if they may have been exposed to a serious communicable disease.
3. Another important change relates to the antiretroviral drugs recommended for use in PEP starter packs. Annex C now recommends nelfinavir as the protease inhibitor of choice alongside zidovudine and lamivudine, consistent with current best practice.
4. Other amendments address specific enquiries on the guidance received and considered by EAGA or new evidence. These include: further clarification on how and when a source patient should be approached for HIV testing (paragraphs 27 and 29); how long blood samples taken as part of management of an occupational exposure need to be stored (paragraph 43); and advice to exclude nevirapine from routine PEP regimens following reports of serious adverse effects (Annex C, paragraph 12).
5. The main sections of this guidance apply to occupational exposure of health care workers in the health care setting to material which is known to be, or has the potential to be a source of HIV infection.
6. However, **any** person significantly exposed to risk of HIV infection in a health care setting (including a domiciliary care situation) should be assessed and managed according to the principles in this guidance, whether or not they are a health care worker. Examples would include relatives or friends providing care in the home, hospital domestic and waste disposal staff. If a child is exposed, specialist advice from a paediatrician with experience in the HIV field should be sought.
7. 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, 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.

1.2 General principles

8. Occupational exposure to 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. The recommendations of EAGA and the Advisory Group on Hepatitis (AGH) in “Guidance for Clinical Health Care Workers: Protection Against Infection with Blood-borne Viruses” [2], if scrupulously observed, will serve to reduce the incidence of occupational exposures to a minimum. All the general principles of those recommendations, set in the context of health and safety legislation, are relevant to the issue of blood-borne virus (including HIV) occupational exposure. It is important that they should be read in conjunction with this guidance.
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). In the EAGA/AGH guidance referred to above [2], the chapter on “Management of Blood Exposure Incidents” recommends an integrated approach to post-exposure management with respect to HIV, HBV and HCV.
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. 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. This policy must ensure that adequate 24-hour cover is available and should designate one or more doctors to whom exposed persons may be referred urgently for advice. Primary responsibility should lie with the occupational health service, with out-of-hours cover provided by accident and emergency departments, unless there are other arrangements locally for out-of-hours cover to be provided by, for example, occupational health services. Accident and emergency 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 (CDC) concluded that the administration of zidovudine prophylaxis to health care workers occupationally exposed to HIV was associated with an 80% reduction in the risk for occupationally acquired HIV infection [3]. 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
16. It was estimated that the risk for HIV transmission after percutaneous exposures involving larger volumes of blood, 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 indicates 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 increased prevalence of zidovudine resistance amongst HIV-infected people, 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 post-exposure prophylaxis (PEP) with antiretroviral drugs and recommends that their use should be considered in certain circumstances. Additional references [4-8] are included in Annex H for those who seek more detailed consideration of the accumulated evidence supporting the efficacy of HIV PEP, and of potential disadvantages.

20. 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
- the issue of health care workers seconded overseas, including medical students on 'electives'
- the issue of PEP in relation to exposure to HIV outside the health care setting
- antiretroviral drug resistance
- laboratory workers (including virologists) 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
- PEP for patients after possible exposure to an infected health care worker

CHAPTER 2

RISK ASSESSMENT

2.1 Immediate action

21. 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.
22. The exposed health care worker should be aware about local arrangements for access to urgent advice about occupational exposure and PEP. A risk assessment needs to be made urgently by someone other than the exposed worker about the appropriateness of starting PEP, ideally a 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 (if the exposed worker is not immune) and hepatitis C. Guidance on an integrated approach to post-exposure management is provided in 1998 guidance from EAGA and the AGH [2].

2.2 Circumstances of exposure

23. 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.
24. 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);
 - (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]

25. 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 The source patient

26. 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 that the exposed worker takes the first dose of PEP pending the outcome of a more thorough risk assessment to inform a decision whether to continue the regimen (see also paragraphs 37 and 38).
27. The designated doctor should normally make arrangements 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.** 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 the appearance of discrimination against people perceived as belonging to groups associated with higher than average HIV prevalence. However, there may be occasions when a preliminary risk assessment may be helpful in avoiding inappropriate HIV testing.
28. When a source patient is asked to agree to be tested for HIV antibodies, careful pre-test discussion will be needed, as will informed consent [9]. This pre-test discussion can be provided by any appropriately trained and competent health care worker [10]. Specialist pre-test counselling may sometimes be considered appropriate if the circumstances of the source patient are unusual or complex.
29. 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.
30. As part of pre-test discussion, or prior to 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 and request for a test. 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. It is understood that consent to HIV testing is rarely withheld in these circumstances, when the approach is made in a sensitive manner.

31. The use of codes as identifiers should be considered when requesting HIV testing of source patients and exposed workers in connection with an exposure incident, as an additional safeguard for confidentiality.
32. The General Medical Council's ethical statement *Serious Communicable Diseases* includes a section about injuries to health care workers and the issues of source patient testing, consent and testing of existing blood samples. It includes a consideration of situations where consent to testing for serious communicable diseases cannot be obtained, for instance in the unconscious patient. This is reproduced at Annex B and should be read in conjunction with this guidance.
33. 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 counselling appropriate to individual circumstances.

2.4 The unknown source

34. If there has been a significant exposure and a source patient cannot be identified, risk assessment should be on an individual basis. This will be informed by a consideration of the circumstances of the exposure, and the epidemiological likelihood of HIV in the source. In the vast majority of such exposures, it would be difficult to justify the use of PEP.

CHAPTER 3

PEP

3.1 When to prescribe PEP

35. PEP should be recommended to health care workers if they have had a significant occupational exposure (see paragraph 24) 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.
36. PEP should not be offered after exposure through any route with low risk materials (e.g. urine, vomit, saliva, faeces) unless they are visibly blood stained. 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.
37. When offering PEP it is important to take into account any views of the exposed health care worker. Depending on the outcome of 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, as appropriate if further information becomes available.
38. 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 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.
39. The relative risk of transmission may be increased considerably if the source patient has a high viral load (e.g. at the time of seroconversion or in the later stages of HIV disease). There is no reassurance that the converse applies i.e. when a source patient's viral load was low when last measured.

3.2 What to prescribe for PEP

See Annex C.

3.3 Management of health care workers occupationally exposed to HIV – further issues

40. Occupational exposure to known or suspected HIV-infected materials is always stressful and for some, extremely so.
41. Although PEP ideally should be commenced as soon as possible after the event, if a longer interval has elapsed following possible exposure this may not be a contra-indication to starting therapy. The kinetics and early pathogenesis of HIV are not fully understood and it may still be worth

considering starting PEP even if up to 2 weeks have elapsed since the exposure. The guidance given on risk assessment earlier in this document would still be relevant.

42. 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 are 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.
43. The evaluation of the health care worker should include a medical history. Details of any existing medication should be established (including oral contraception – 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 paragraph 51). The practice of taking a 6-month sample for storage only should be discouraged. 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.
44. It is important that all information about the health care worker and the source patient is kept confidential. Arrangements will need to be in place to ensure this, including the use of codes as identifiers where appropriate.
45. 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 nelfinavir.
46. Regular medical follow-up during the period of PEP is necessary to monitor acceptability and possible toxicity of the preparation(s). Close follow-up and encouragement, ideally on a weekly basis at least, from an experienced occupational health practitioner, is likely to help improve adherence and deal expeditiously 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.
47. In line with EAGA's HIV-infected health care worker guidance [11], 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. All 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).

48. Pending follow-up and in the absence of seroconversion, health care workers need not be subject to any modification of their working practices, for example avoidance of exposure-prone procedures, defined according to criteria given in the guidance referred to above [11]. Advice should, however, be given about safer sex and avoiding blood donation during the follow-up period.

3.4 HIV seroconversion

49. If during the follow-up period HIV infection is diagnosed, the health care worker should be advised and managed in line with EAGA recommendations [11]. Although HIV is not a prescribed disease under the Social Security Acts, health care workers who have acquired HIV infection because of exposure to HIV-infected material in the workplace may be able to claim Industrial Injuries Disablement Benefit where there has been an accident arising out of and in the course of employment, e.g. a significant occupational exposure such as a needlestick injury.
50. The NHS Injury Benefits Scheme (or HPSS Injury Benefits Scheme in Northern Ireland) provides temporary or permanent benefits for all NHS employees who lose remuneration because of an injury or disease attributable to their NHS employment. 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 balance of probabilities, the injury or disease was acquired during the course of NHS work.
51. At least 6 months should elapse after cessation of PEP before a negative antibody 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.
52. 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.

3.5 Making PEP available: immediate access

53. It is recommended that, for optimal efficacy, PEP should be commenced as soon as possible after the incident and ideally within the hour. 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.

54. Starter packs of the recommended drugs should be kept in a number of readily accessible and well advertised places including:
- Occupational Health Department
 - Pharmacy
 - Accident & Emergency (A&E) Department
 - Specific wards or departments
55. Each pack should contain a 3-day course of the drugs sufficient to cover weekends and bank holidays, two packs to be given to cover longer bank holiday weekends.
56. 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.
57. 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

58. Consultants in Communicable Disease Control or, in Scotland, Consultants in Public Health Medicine (CD & EH) should 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. 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 contracting process, these arrangements should be audited.
59. It is recommended that every NHS body or other health care setting should develop a post-exposure policy and a protocol. Where appropriate, standard 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.
60. Managers should ensure that PEP policies and protocols reflect current best practice.
61. 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 about 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).
62. Local factors will vary between Trusts and other health care settings and first-line provision of PEP will depend on these.

63. Sources of expert advice should be indicated in local policies and may include:
- Consultants in Virology, Microbiology, Infectious Diseases, HIV medicine, G.U. Medicine, Occupational Health;
 - 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).
64. 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.
65. 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.
66. 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 normally would be expected to assume responsibility for assessment of occupational exposure and PEP, and will be the first point of contact for any such exposure, whether or not this arose in the hospital. 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
67. In other health care settings it will be important for general medical practitioners 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 that involves a risk of exposure to HIV-infected material, they should be advised about infection control measures to prevent exposure [2,13], and the importance of reporting any exposure incidents to the accident and emergency department without delay.
68. Those responsible for occupational health and safety of certain non-health care workers (such as police, fire service and prison service personnel), who may also be at risk of occupational exposure to HIV, should ensure there are similar arrangements in place for access to advice in such an emergency, and assessment and treatment where appropriate.

69. Backup 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 63 above.
70. 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.
71. 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 24, 25);
 - 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 occupational health department 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 CDSC (HPA) or, in Scotland, to the Scottish Centre for Infection and Environmental Health (SCIEH) (see Annex D, paragraphs 1 and 2). Specific types of accident, and development of HIV disease as a consequence of occupational exposure, are required to be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences (RIDDOR) legislation (see Annex D, paragraphs 3-5);
 - local procedures for reporting accidents and keeping lists of laboratory employees intentionally working with Hazard Group 3 pathogens (COSHH schedule 3).

72. **Staff training** issues include:
- avoidance of occupational exposure to HIV by adherence to safer working practices and use of personal protective equipment as appropriate [2];
 - 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;
 - training of junior staff (e.g. triage nurses and junior doctors in Accident and Emergency 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.
73. The OH 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;
 - to inform staff training as appropriate.
74. 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

75. 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.
76. 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 [2,14]. These principles should be introduced in medical, dental school and nursing training curricula prior to the start of clinical attachments, 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.
77. The prevalence of HIV infection in some areas overseas is relatively much higher than that in the UK [15]. Infection control precautions to prevent possible blood-borne virus exposure may be more difficult to implement in some less developed countries. The likelihood of an occupational exposure, and in turn the likelihood that that exposure will be to HIV-infected material, will be considerably higher in some circumstances than in the UK setting [16-18].
78. 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. A Health Education Authority booklet on behalf of the UK NGO AIDS Consortium, "HIV/AIDS and working overseas: A guide for employees" [19] provides some useful general background material, although its reference to PEP is based on the guidelines issued in 1997 which have been superseded.
79. 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. Specific consideration should be given to the risk of occupational exposure to HIV and how to minimise this.
80. 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 complete dental and medical training (if performing exposure-prone procedures is necessary to achieve this). Limitation of future career choices in the event of HIV infection for a student who is able to complete training, or other health care worker depending on their discipline, should be carefully explained [11]. 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.

81. Pre-travel briefing might include reinforcement of advice on immediate post-exposure first aid measures (see paragraph 21), and training on self-assessment of occupational exposure as to whether an exposure is, or is not significant with the potential to transmit HIV, as considered earlier in this document (paragraph 24). 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.
82. 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 phone from the UK source of expert advice to their own employer/medical school.
83. Employers, 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. EAGA recommends that those travelling to, and who may be occupationally exposed in countries where zidovudine resistant virus is much less likely to be encountered, should take PEP starter packs with them containing zidovudine in combination with lamivudine. Difficulties may arise if protease inhibitor drugs are taken unsupervised. Any student/other worker issued with a starter pack including a protease inhibitor should be warned about increased toxicity in the event of dehydration.
84. 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.
85. 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. EAGA is aware that one medical school has negotiated an inexpensive group arrangement with a travel insurance company for urgent repatriation of students who have had significant occupational exposures overseas. The desirability of adding a protease inhibitor for the remainder of the 4-week regimen can be considered on return to the UK, or if a specialist centre can be accessed overseas.
86. 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 [12]. On return from working abroad in countries of high HIV prevalence, health care workers including students should be asked to complete a questionnaire about possible significant exposures in circumstances of high HIV prevalence. This will alert the occupational health department to the need for any more detailed debriefing. After discussion of the risk(s) to which they may have been exposed, HIV testing may be considered appropriate (in reference [11] - paragraphs 4.5-4.6). Of the eight 'probable' occupationally acquired HIV infections reported in the UK, seven were associated with exposure in high prevalence areas abroad [8].

87. The outcomes of such debriefing will help medical, dental and nursing schools steer future students away from placings 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 HEALTH CARE SETTING

88. For the purposes of this document, exposure outside the health care setting may include sexual exposure to HIV, sharing drug injecting equipment with someone with HIV or significant exposure to material which may be infected with HIV in any other circumstance.
89. Those responsible for occupational health provision to people in professions who may be at some risk of exposure to HIV-infected material outside health care settings (e.g. police, fire 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.
90. As for occupational exposure, the most effective methods for preventing HIV infection in all settings are those which protect against exposure to HIV.
91. No data exist on the efficacy of antiretroviral post-exposure prophylaxis following exposure to HIV other than for occupational exposure in a health care setting. EAGA is aware that some physicians have prescribed PEP outside the occupational exposure context, on an individual case-by-case basis. However, due to lack of any evidence of efficacy, at present EAGA cannot recommend in favour of, or against its use. A selection of references of relevance to this issue is provided in Annex H [20-30].
92. Exposures outside the health care setting which may give rise to requests for PEP include: rape (whether or not the HIV status of the source is known), condom breakage during sex between HIV discordant partners, and having shared drug injecting equipment. There are other circumstances where individuals may be exposed to blood or other material that may pose a risk of HIV transmission [31]. Such exposures may give rise to requests for PEP, or the need to consider it. After an exposure outside the health care setting that is considered to carry a high risk of HIV infection, expert advice should be sought urgently from a physician experienced in the treatment of HIV and familiar with considerations for the use of PEP. If a child has been exposed, specialist advice from a paediatrician experienced in the field of HIV should be sought.
93. Sexual exposure can also place a person at risk of other sexually transmitted infections, and of pregnancy. Exposure through sharing drug injecting equipment can expose a person to 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. Where unintended pregnancy is a possible outcome, emergency contraception should be offered.
94. Factors influencing the potential efficacy of non-occupational PEP include the probability that the sexual partner, or injecting equipment sharer is HIV infected, the likelihood of transmission by the particular exposure, the interval between the exposure and initiation of PEP, the efficacy of the drugs used, and the exposed person's adherence to the PEP regimen.

95. The circumstances of the exposure should inform a discussion about the perceived risk of HIV acquisition. It is recognised that the sexual exposure of greatest risk is receptive anal exposure to an HIV-infected partner [31]. The risk associated with receptive vaginal exposure is of a similar order to percutaneous (occupational) exposure [32]. The risk per episode of injecting equipment exposure is probably intermediate [33]. In all circumstances published estimates of overall incidence for a particular exposure can serve only as a guide, since individual factors may increase or decrease risk. If it is known that the viral load of a source had been below the limit of detection around the time of the exposure, or consistently for a period prior to the exposure, it seems likely that the risk of HIV transmission to a sexual or injecting partner would be low [34]. Otherwise, because of the potential for fluctuation of viral load, the fact that viral load was low on the last occasion of testing does not provide reassurance that it would also have been low at the time of the exposure which is being considered.
96. Following occupational exposure, source patients and their records including information about past and current antiretroviral therapy and possible resistance are often available. By contrast, even when it is known or considered highly likely that a non-occupational source is HIV infected, such detail may be less readily available. In coercive situations e.g. rape, scant (if any) detail may be available about the source. Lack of information makes it difficult to tailor antiretroviral therapy if used as PEP for an exposed person, increasing the risk of infection with a drug resistant strain of HIV in the event of PEP failure. This outcome is all the more likely if adherence to the PEP regimen is sub-optimal.
97. For optimal efficacy, ideally PEP should be started within an hour of exposure (see paragraph 53). Presentation following a non-occupational exposure is unlikely to be sufficiently prompt to derive maximum benefit from PEP, and the risk of its failure is consequently increased. However, longer periods from exposure are not considered an absolute contraindication to PEP (see paragraph 41).
98. A doctor considering the prescription of PEP after an exposure outside the health care setting should make an individual risk assessment of the circumstances of the exposure. If approaching the source to seek consent to HIV testing is feasible, the considerations earlier in this document (section 2.3) should apply.
99. Doctors should be aware that if PEP has the potential to be effective after non-occupational exposure, benefits are more likely in situations where:
- the risk of HIV transmission is considered high;
 - such exposure is considered unlikely to be repeated;
 - PEP can be started promptly;
 - good adherence to the regimen is considered likely.

100. Informed consent should be obtained from the exposed person prior to prescribing PEP. The exposed person's understanding of the following should be documented:

- the need to start or resume relevant measures to reduce risk of exposure to HIV;
- lack of evidence of efficacy of PEP in these circumstances and the differing views of experts about its use in this context;
- known side effects and unknown toxicity of the drugs to be prescribed;
- the importance of close adherence which may improve any efficacy and reduce the risk of infection with drug-resistant HIV, should infection supervene despite PEP;
- arrangements for follow-up;
- symptoms and signs which may be associated with HIV seroconversion.

101. All the considerations in this document which apply to the prescription of PEP after occupational exposure apply equally to non-occupational PEP from the point of a decision being reached that it is appropriate to prescribe it. In particular, Annex E is of relevance to exposed women who are or may be pregnant, including any who may become pregnant as a result of the exposure for which PEP is being considered.

102. To assist in the accumulation of epidemiological evidence on the use and efficacy of non-occupational PEP, any doctors prescribing it are encouraged to keep well-documented records of individual cases on an ongoing basis. Such records should include:

- information about the circumstances of the exposure;
- details of the source and their HIV medication if known;
- the time between exposure and starting PEP;
- drugs prescribed;
- compliance with the regimen;
- adverse effects of the drugs;
- results of follow-up testing for HIV infection.

Well-documented records would also facilitate responses to any audits and surveillance of non-occupational PEP use in the future.

Note: Guidelines for the provision of PEP following sexual exposure are being prepared by the HIV Special Interest Group of the British Association for Sexual Health and HIV (BASHH) and will be posted on their website when finalised.

Body fluids and materials which may pose a risk of HIV transmission if significant occupational exposure occurs

Amniotic fluid

Cerebrospinal fluid

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)

Synovial fluid

Unfixed human tissues and organs

Any other body fluid if visibly bloodstained

Exudative or other tissue fluid from burns or skin lesions

Vaginal secretions

Semen

**Extract from *Serious Communicable Diseases:*
General Medical Council 1997**

Injuries to health care workers

8. *If you or another health care worker has suffered a needlestick injury or other occupational exposure to blood or body fluids and you consider it necessary¹ to test the patient for a serious communicable disease, the patient's consent should be obtained before the test is undertaken. If the patient is unconscious when the injury occurs consent should be sought once the patient has regained full consciousness. If appropriate, the injured person can take prophylactic treatment until consent has been obtained and the test result is known.*
9. *If the patient refuses testing, is unable to give or withhold consent because of mental illness or disability, or does not regain full consciousness within 48 hours, you should reconsider the severity of the risk to yourself, or another injured health care worker, or to others. You should not arrange testing against the patient's wishes or without consent other than in exceptional circumstances, for example where you have good reason to think that the patient may have a condition such as HIV for which prophylactic treatment is available. In such cases you may test an existing blood sample, taken for other purposes², but you should consult an experienced colleague first. It is possible that a decision to test an existing blood sample without consent could be challenged in the courts, or be the subject of a complaint to your employer or the GMC. You must before be prepared to justify your decision.*
10. *If you decide to test without consent, you must inform the patient of your decision at the earliest opportunity. In such cases confidentiality is paramount: only the patient and those who have been exposed to infection may be told about the test and its result. In these exceptional circumstances neither the fact that the test has been undertaken, nor its result, should be entered in the patient's personal medical record without the patient's consent.*
11. *If the patient dies you may test for a serious communicable disease if you have good reason to think that the patient may have been infected, and a health care worker has been exposed to the patient's blood or other body fluid. You should usually seek the agreement of a relative before testing. If the test shows the patient was a carrier of the virus, you should follow the guidance in paragraphs 22-23 of this booklet on giving information to patients' close contacts.*

¹Wherever possible you should consult an occupational health physician or other suitably qualified colleague before making a decision about testing.

²Taking blood from a patient without consent may leave you open to criminal charges.

Responsibilities of doctors who have been exposed to a serious communicable disease

29. *If you have any reason to believe that you have been exposed to a serious communicable disease you must seek and follow professional advice without delay on whether you should undergo testing and, if so, which tests are appropriate. Further guidance on your responsibilities if your health may put patients at risk is included in our booklet Good Medical Practice.*
30. *If you acquire a serious communicable disease you must promptly seek and follow advice from a suitably qualified colleague - such as a consultant in occupational health, infectious diseases or public health on:*
 - *Whether, and in what ways, you should modify your professional practice.*
 - *Whether you should inform your current employer, your previous employers or any prospective employer, about your condition.*
31. *You must not rely on your own assessment of the risks you pose to patients.*
32. *If you have a serious communicable disease and continue in professional practice you must have appropriate medical supervision.*
33. *If you apply for a new post, you must complete health questionnaires honestly and fully.*

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 analogue reverse transcriptase inhibitors [NRTIs]
 - non-nucleoside reverse transcriptase inhibitors [NNRTIs]
 - 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 [3]. It continues to be reasonable that zidovudine is included in all first choice PEP regimens.
3. No antiretroviral drug has been licensed for post-exposure prophylaxis. These drugs can be prescribed for PEP only on an 'off-label' basis since their use in this context is outside approved indications.
4. In HIV-infected patients, combination drug therapy has proved more effective than zidovudine alone in reducing viral load. In theory, a combination of drugs could increase potency of post-exposure prophylaxis and offer increased protection, in view of the increased prevalence of resistance to zidovudine and other antiretrovirals [35].
5. 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 choice of PEP drugs (see Annex E).
6. Since 2000, the recommended drugs for PEP starter packs have been zidovudine, lamivudine and either indinavir or nelfinavir. However, indinavir is relatively poorly tolerated and is now rarely used in the treatment of HIV infection. National surveillance of PEP use following occupational exposure to HIV indicates a higher incidence of discontinuation of indinavir-based regimens due to side effects (CDSC, unpublished data) and indinavir is no longer considered suitable for use in PEP regimens. The recommended drugs for PEP starter packs are now:

zidovudine 250mg or 300mg b.d.

plus

lamivudine 150mg b.d.

plus

nelfinavir 1250mg b.d. (or 750mg t.d.s)

7. 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 PIs that may be considered would include ritonavir-boosted lopinavir, saquinavir or amprenavir.

Side effects

8. 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. zidovudine and lamivudine) have been mainly gastrointestinal (e.g. nausea, vomiting). Malaise, fatigue and headache have also been reported. Some experts consider that stavudine may be substituted for zidovudine as a means of reducing adverse effects, and others consider that zidovudine should not be omitted from any PEP regimen (see paragraph 2 above).
9. 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.
10. Protease inhibitor drugs may have potentially serious interactions with other prescribed drugs. The examples provided below are by no means exhaustive. Some sources of further advice about drug interactions are provided at Annex F.
11. Nelfinavir frequently causes diarrhoea. It may accelerate the clearance of certain drugs including oral contraceptives, resulting in reduced contraceptive efficacy. Protease inhibitors have been associated with new onset, and exacerbation, of existing diabetes mellitus.
12. Both NNRTIs licensed for treatment (nevirapine and efavirenz) are associated with short-term toxicity, nevirapine with the potential for severe rashes (which may be confused with rash associated with HIV seroconversion) and sometimes Stevens-Johnson syndrome. Efavirenz is associated with neurological side effects but has a lower incidence and severity of rash. Following reports of serious adverse events (including life-threatening hepatotoxicity) in health care workers taking nevirapine as part of PEP [36,37], such regimens should not routinely be used for PEP (occupational or non-occupational). These findings do not apply to nevirapine use in other settings (e.g. for reducing vertical transmission of HIV [38]). Evidence on the tolerability and outcome of different PEP regimens will be kept under review.
13. If symptoms believed to arise from PEP are distressing, 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. Adverse reactions associated with antiretroviral drugs should be reported (on the HIV ADR Reporting Form) to:

HIV Adverse Drug Reactions Reporting Scheme
MHRA (medicines)
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Telephone: 020 7273 0153 Fax: 020 7273 0060

Website:

<http://medicines.mhra.gov.uk/ourwork/monitorsafequalmed/adrschemes/hivadrscheme.htm>

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;
 - when the potential for interaction with other medications is recognised (see Annex F);
 - when there is a 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.

Reporting of occupational exposures to HIV

Reporting to HPA Communicable Disease Surveillance Centre (CDSC) or, in Scotland, to the Scottish Centre for Infection & Environmental Health (SCIEH)

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 CDSC or SCIEH. 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;
 - the side effects and benefits of prophylaxis may be assessed.
2. For further details and reporting forms please contact HPA AIDS Centre, CDSC, 61 Colindale Avenue, London NW9 5EQ (Tel. 020 8200 6868) or, in Scotland, SCIEH, Clifton House, Clifton Place, Glasgow, G3 7LN (Tel. 0141 300 1100). Summaries of the data collected can be found at:
http://www.hpa.org.uk/infections/topics_az/bbv/s_report.htm

Reporting of Occupational Exposure to HIV to the Health and Safety Executive (HSE)

3. 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.”*
4. 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.”*
5. HSE have an InfoLine (0870 545500) for general queries relating to RIDDOR or COSHH. Reports under RIDDOR can be made by contacting 0845 3009923 or electronically via the HSE website <http://www.riddor.gov.uk/>

Serious Untoward Incident Reporting System

6. Pending national guidance on reporting serious untoward incidents, Trusts should follow local policies on reporting occupational exposures to HIV where these fall into the scope (e.g. causing serious injury or major permanent harm).

PEP: special circumstances**Viral drug resistance***Source patient*

1. 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. Antiretroviral drug resistance profiling is widely available, and its results, if available, should be taken into account when selecting PEP drugs. Specialist advice should be sought.

Laboratory staff

2. Similarly, in the case of laboratory-based staff, knowledge about the source virus may be very important. This would be the case particularly if a virus with multiple nucleoside analogue resistance and/or protease inhibitor resistance was being handled.

Pregnancy

3. 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.
4. The available evidence is that zidovudine and lamivudine are not contraindicated in the second and third trimesters of pregnancy. Whilst experience is not extensive, there has been no indication of particular problems for the babies of HIV-infected women who have become pregnant whilst already on antiretroviral medication. It should be noted that there is limited experience of the use in pregnancy of some of the newer drugs, including NNRTIs and protease inhibitors.
5. 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 everything that 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.
6. Decisions on the use of specific drugs in pregnancy may be influenced by their individual adverse effects. For example, drugs which may cause nausea may exacerbate pregnancy-associated nausea.
7. The British HIV Association has published guidelines for prescribing antiretroviral therapy in pregnancy [39].

Interactions of antiretroviral medications with commonly used medicinal products

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

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

PEP for patients after possible exposure to an infected health care worker

Blood exposure incidents

1. Implementation of the recommendations in *AIDS/HIV Infected Health Care Workers: Guidance on the Management of Infected Health Care Workers and Patient Notification* [11] 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 procedures³ 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.
2. Three 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)
 - in the unlikely event that an invasive device or product contaminated by use on one patient is accidentally re-used on another patient⁴.

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

3. Both in its guidance *Good Medical Practice* [40] and again in its guidance *Serious Communicable Diseases* (see Annex B, paragraphs 29-33), the General Medical Council 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 cooperates fully with those conducting the risk assessment, providing all necessary information about their own infection status or risk behaviour.

³Exposure-prone procedures are those in which there is a risk that injury to the health care worker could result in exposure of the patient's open tissues to the blood of the health care worker. Such procedures occur mainly in surgery (including some procedures in minor surgery carried out by GPs), obstetrics & gynaecology, dentistry and midwifery. An illustrative list of exposure-prone procedures is contained in reference 11.

⁴Potential patient to patient transmissions should be assessed following usual guidance on source patient testing (see Section 2.3).

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 [11], each NHS body should designate one or more doctors⁵ 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 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 laceration⁶ 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.
 - An instrument or needle contaminated with the blood of the health care worker is 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.
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

⁵Examples 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.

⁶Most needlestick/puncture wounds would be excluded from consideration unless they resulted in significant bleed-back into the patient.

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 hepatitis B 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 indicated⁷.
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 paragraph 16) should only be offered and recommended following a positive test in the health care worker. This recognises that health care workers who are following the Department's guidance [11] are at low-risk for HIV infection and that there are considerable practical difficulties to 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. high likelihood of HIV infection in the health care worker 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.

⁷ No PEP is currently available for hepatitis C. However, a recent study suggests that early treatment of acute hepatitis C infection may prevent chronic hepatitis C infection [41]. Follow-up of exposed patients should follow that described in management for occupational exposure to hepatitis C [42]. A course of hepatitis B vaccination with or without immunoglobulin may be recommended as PEP following exposure to hepatitis B [2].

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.

Follow-up of patients exposed to HIV-infected blood

18. The guidance on follow-up for health care worker's 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

19. *The health care worker who refuses a blood test*
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. A health care

worker who unreasonably refuses a blood test may be in breach of his/her ethical and legal duty of care to patients if it results in the patient receiving PEP unnecessarily. Whilst a health care worker could allege that his/her right to respect for private life under article 8(1) of the European Convention on Human Rights [43] is infringed as a result of being asked to undergo a test, and to action being taken if he/she refuses, it is considered that any infringement would be justifiable under article 8(2), in the interests of protecting the health of others.

20. *The unconscious patient*

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.

21. *The nil-by-mouth patient*

Antiretroviral drugs are available in a number of formulations suitable for naso-gastric or intravenous administration (see Table). 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: Antiretroviral formulations suitable for naso-gastric or intravenous administration

Drug	Strength	Route of administration	Dose
Nucleoside reverse transcriptase inhibitors			
Abacavir oral solution	20mg/ml	Naso-gastric	15ml bd (300mg bd)
Didanosine powder for oral solution (unlicensed)	10mg/ml	Naso-gastric	40ml od (400mg od)
Didanosine tablets	25mg 100mg 200mg	Naso-gastric	400mg od
Lamivudine oral solution	50mg/5ml	Naso-gastric	15ml bd (150mg bd)
Stavudine powder for oral solution	1mg/ml	Naso-gastric	40ml bd (40mg bd)
Zidovudine oral syrup	50mg/5ml	Naso-gastric	25ml bd (250mg bd)
Ziduvudine injection	10mg/ml	Intravenous	25ml IV bd (250mg bd)
Protease inhibitors			
Amprenavir oral solution	15mg/ml	Naso-gastric	Liquid has lower bioavailability than the capsules therefore not equivalent mg for mg. Dose = 17mg (1.1ml) per kg tds, up to maximum of 2800mg total daily dose.
Nelfinavir oral powder	50mg/gram	Naso-gastric	25gram bd (1250mg bd)
Lopinavir with ritonavir oral solution	400mg and ritonavir 100mg in 5ml	Naso-gastric	5ml bd (400mg/100mg bd)
Ritonavir oral solution	400mg/5ml	Naso-gastric	7.5ml bd (600mg bd)
Non-nucleoside reverse transcriptase inhibitors*			
Nevirapine oral suspension	50mg/5ml	Naso-gastric	20ml bd (200mg bd)
Efavirenz oral liquid	30mg/ml	Naso-gastric	Liquid has lower bioavailability than capsules therefore not equivalent mg for mg. 600mg capsule dose = 720mg liquid (24ml)
Delavirdine tablets (unlicensed)	100mg	Naso-gastric (dissolve in acidic drinks e.g. cola)	6 tablets bd (600mg bd)

Some drugs require dose reduction in patients weighing less than 60kg and also in the presence of drug interactions. These have not been taken into account in the above table. *See Annex C paragraph 12 for caveats around the use of non-nucleoside reverse transcriptase inhibitors.

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