HIV post-exposure prophylaxis (PEP) policy following occupational exposure to HIV in the health care setting

POLICY

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	X		
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Sponsor (Position)	Medical Director		
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Lead Division/ Directorate	Corporate		
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Position of Person able to provide Further Guidance/Information	Consultant Occupational Physician		

Associated Documents/ Information	**Date Associated Documents/ Information was reviewed**
1. Source patient consent leaflet reviewed and updated with this policy (accessible on OH intranet site) Sharps injury source patient consent leaflet)	May 2021
Template control	June 2020

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1.0 INTRODUCTION

1. This policy document incorporates the latest guidance on occupational HIV post-exposure prophylaxis (PEP) from the British Association for Sexual Health and HIV UK Guideline for the use of HIV post exposure prophylaxis which was published in 2021 and updated on 16 April 2021 (9) and which supersedes guidance from the UK Chief Medical Officer's Expert Advisory Group on AIDS (EAGA) published in September 2008 (1).

2. This policy document offers guidance on:
   (i) assessing the risk of a health care worker acquiring HIV infection following occupational exposure;
   (ii) when to recommend HIV PEP;
   (iii) the choice of drugs;
   (iv) how to ensure that all health care workers have immediate, 24 hour access to HIV PEP and to appropriate advice and support; and
   (v) HIV PEP for female health care workers who are, or may be, pregnant.

This policy is issued and maintained by the Medical Director (the sponsor) on behalf of The Trust, at the issue defined on the front sheet, which supersedes and replaces all previous versions.

2.0 POLICY STATEMENT

- Occupational exposure to blood and body fluids is relatively common. Many exposures result from a failure to follow recommended procedures, including the safe handling and disposal of needles and sharps, and the wearing of personal protective eyewear.

- Any significant exposure to blood and other body fluids or tissues has the potential to transmit HIV and other blood-borne viral infections, such as hepatitis B (HBV) and hepatitis C (HCV).

- There will remain occasions when exposure occurs despite the correct procedures having been followed.

- All 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 needle stick injury or other occupational exposure.

- The Department of Health states that every NHS employer should have a written policy on the management of blood and body fluid exposures, which should specify the local arrangements for risk assessment, advice and the provision of HIV PEP. This policy must ensure that adequate 24 hour cover is available. It suggests that primary responsibility for managing all blood and body fluid exposures lies with the occupational health service, with out-of-hours' cover provided by Emergency Departments (E.D.)

3.0 DEFINITIONS/ ABBREVIATIONS

The Trust	Sherwood Forest Hospitals NHS Foundation Trust
Staff	All employees of the Trust including those managed by a third party organisation on behalf of the Trust
High risk bodily fluids include:	blood, amniotic fluid, vaginal secretions, semen, human breast fluids, milk, cerebrospinal fluid, peritoneal fluid, pleural fluid, synovial fluid, pericardial fluid, saliva in association with dentistry, unfixed tissues and organs, any other body fluid if visibly blood-stained, exudative or other tissue fluid from burns or other lesions.
PEP	Post Exposure Prophylaxis

4.0 ROLES AND RESPONSIBILITIES

4.1 The Chief Executive retains the overall responsibility for the implementation of this policy throughout the Trust; however he/she delegates to Line Manager/ Department or Ward Leader or Deputies the particular responsibility for ensuring that the policy, as it relates to hazards which arise during the day to day activities of the Trust, is implemented.

4.2 All **Directors and Divisional Managers** have responsibility for ensuring that all arrangements made under this policy are implemented appropriately. This includes:

4.2.1 Setting Unit and Directorate objectives and targets concerned with the control of sharps use and injuries.

4.3 Each **Operational Manager** shall develop/ implement measures to ensure compliance with the Sharps Policy and departmental procedures. In particular they shall:

4.3.1 ensure that all staff receive adequate information, instruction and supervision;

4.3.2 ensure that all necessary risk assessments have been undertaken and where appropriate the results recorded;

4.3.3 ensure appropriate compliance with the hepatitis B vaccination protocol;

4.3.4 complete any necessary further investigation into any reported accident or incident involving sharps and where appropriate produce a report.

4.4 Trends and occurrence of needlestick/sharps injuries will be monitored through the Datix incident reporting system via the Trust's **Health and Safety Manager**, the Sharps and Splash Injury Prevention Sub-Group and through monthly audit by Occupational Health. Issues regarding the clinical practice of members of staff involved in sharps/needlestick injuries will be brought to the attention of their appropriate medical or nursing line manager (or Consultant responsible for a Junior Doctor involved), via the Datix incident reporting system. Staff will be involved in further discussion regarding avoidance of subsequent needlestick injuries if appropriate.

4.5 The **Occupational Health Department** is responsible for:

4.5.1 providing advice on sharps matters as required;

4.5.2 assisting in the management of sharps injuries;

4.5.3 providing a vaccination service.

4.5.4 providing a monthly report to the Sharps and Splash Injury Prevention Sub-Group

4.6 **The Infection Prevention and Control Team** has a vital role in controlling the risks associated with the use of sharps including:

4.6.1 to advise employees on the correct use and disposal of sharps in accordance with UK legislation 'The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013'.

4.6.2 to audit sharps management, from commencement of a process to disposal across the organisation using both external and internal sources

4.6.3 to promote a 'hierarchy of controls' to ensure the most effective measures available are used: use of personal protective equipment; eliminate recapping needle; training and education; to promote safer devices and ultimately to eliminate the need for sharps to be used.

4.7 All **employees** are required to:

4.7.1 take reasonable care for the health and safety of themselves and of other persons who may be affected by their acts or omissions;

4.7.2 co-operate with the Trust so as to enable it to perform or otherwise comply with its statutory duties by complying with this policy;

4.7.3 not intentionally or recklessly interfere with or misuse anything provided in the interests of health, safety or welfare;

fully comply with the arrangements laid out in Section 6 below

5.0 APPROVAL

Following consultation, this policy has been approved via the Trust's Infection Prevention and Control Committee.

6.0 DOCUMENT REQUIREMENTS

6.1 HIV and significant occupational exposure

- The risk of acquiring HIV infection following occupational exposure to HIV-infected blood is low. Epidemiological studies have indicated that the risk of HIV transmission after percutaneous exposure to HIV-infected blood in health care settings is no more than 3 per 1,000 injuries and is likely to be lower than this. Following a muco-cutaneous exposure, the average risk is estimated at less than 1 in 1,000. There is no risk of HIV transmission where intact skin is exposed to HIV-infected blood.

- 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% relative reduction in the risk of occupationally acquired HIV infection (2).

  Four factors are associated with increased risk of occupationally acquired HIV infection:
  1. deep injury;
  2. visible blood on the device which caused the injury;
  3. injury with a needle which had been in a source patient's artery or vein;
  4. end stage HIV-related illness in the source patient, where the source patient has a very high viral load.

- 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.

- In established HIV infection, combinations of antiretroviral drugs are more potent than single drugs in suppressing viral replication. This has led to the introduction of combination antiretroviral drug prophylaxis following occupational exposure to HIV.

- Only five cases of definite HIV seroconversion in UK health care workers have been documented following occupational exposure; four occurred in or before 1993, only one of whom received HIV PEP (zidovudine monotherapy). The most recent case was in 1999, when seroconversion occurred despite combination HIV PEP (3).

6.2 Risk assessment

Immediate action – first aid, reporting and risk assessment

- 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 for their efficacy. 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.

- Prompt reporting of injuries is a necessary first step to enabling appropriate and rapid access to HIV PEP. A risk assessment needs to be undertaken urgently by someone other than the exposed worker about the appropriateness of starting HIV PEP.

The circumstances of exposure

- HIV PEP should be considered after an exposure with the potential to transmit HIV, based on the type of body fluid or substance involved (appendix A), and the route and severity of the exposure.

- The designated doctor or other practitioner should first assess if the exposure reported by the health care worker is significant – that is, with the potential to transmit HIV. There

are three types of exposure in health care settings associated with the potential to transmit HIV. 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.

- 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 HIV 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.

6.3 Assessment and testing of the source patient

- If initial assessment indicates that an exposure has been significant – that is, with the potential for HIV transmission – consideration should be given to the HIV status of the source patient. It may be possible to ascertain from medical records that a source patient has established HIV infection. Results from animal studies suggest that HIV PEP is most likely to be effective if started within an hour of the incident. An urgent preliminary risk assessment should assess if it is appropriate to recommend taking the first dose of HIV PEP. A more thorough risk assessment can then be undertaken to inform a decision about whether to continue.

- Appropriate arrangements should be made to approach all source patients 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 should be made by another member of the clinical team responsible for the patient. A universal approach to asking source patients to agree to have an HIV test avoids the need to make judgements, simplifies and normalises the process and avoids potential discrimination against people who belong to groups associated with higher than average HIV prevalence (appendix C).

- When a source patient is asked to undergo HIV testing, pre-test discussion will be needed, as will 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 healthcare worker.

  The Trust has a source patient consent leaflet for this situation.
  Sharps injury source patient consent leaflet

- 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 HIV PEP should be based on the available information. Patients who are at high risk of being infected with a blood-borne virus can be offered testing on clinical grounds at any stage

of their care. This is consistent with best practice for improving the detection and diagnosis of HIV in non-HIV specialties advocated by the Chief Medical Officer (4).

- Section 1 (1) (f) of the Human Tissue Act 2004 allows "relevant material", which is defined as anything containing cells, 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 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 event of a deceased patient being the source of a needlestick injury and whose HIV status is unknown, the taking and testing of samples also requires consent in accordance with the Human Tissue Act 2004. Assuming the deceased did not give consent while alive, this can be obtained through a "nominated representative" (if appointed) or by a person in a "qualifying relationship" to the deceased.

- As part of pre-test discussion, and 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, the request for testing and to whom the results will be disclosed. The difficulties of the exposed healthcare worker's situation should be explained – both in terms of the health care worker not missing the opportunity to benefit from HIV PEP and also not being subjected unnecessarily to potentially unpleasant short-term and unknown long-term side effects of the drugs. Consent to HIV testing is rarely withheld in these circumstances. The Trust's source patient consent leaflet should be used in this situation Sharps injury source patient consent leaflet

- Risk factors in the source patient's history for HIV disease include men who have sex with men; female sexual partners of men who have sex with men; past and present injecting drug users who share injecting equipment; and people who have ever had sexual intercourse with someone from an area where HIV is more common, such as Sub Saharan Africa. Further information about HIV seroprevalence rates is contained in appendix C.

- Testing of source patients' blood should be conducted urgently. A negative result should minimise the exposure of the healthcare worker to antiretroviral medication and should also allay the anxiety of the exposed health care worker. It is recommended good practice to obtain an HIV test result within 8 hours and not more than 24 hours after source blood is taken. Starting HIV PEP, where appropriate, should not be delayed while waiting for the result of source patient testing.

- Any source patient who is newly diagnosed with HIV infection will need urgent access to specialist post-test counselling. Source patients should also be informed promptly

  of HIV negative results, with any post-test discussion appropriate to individual circumstances (e.g. to address any 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 assessment of risk for the exposed health care worker.

6.4 Exposure to discarded needle/unknown source

- Where it is not possible to identify the source patient (for example a needle stick injury caused by a discarded needle), a risk assessment should be conducted to determine whether the exposure is significant. This will be informed by considering the circumstances of the exposure and the epidemiological likelihood of HIV in the source. The use of HIV PEP is not recommended following community needlestick exposure (9) where the source can't be identified

6.5 HIV Post Exposure Prophylaxis

When to prescribe HIV PEP

- HIV PEP should be recommended to health care workers if they have had a significant occupational exposure (see paragraph 16) to blood or another high-risk body fluid (see Appendix A) from a patient or other source known to be HIV infected and with an unknown or a detectable (>200 copies/m) viral load (9)

- HIV PEP should not be offered after exposure through any route with low-risk materials (e.g. urine, vomit, saliva, faeces) unless these are visibly bloodstained (e.g. saliva in association with dentistry). Also, HIV 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 unlikely (appendix C). Exceptionally, HIV PEP may be indicated following a negative test if there is good reason to suspect the source may be seroconverting (that is in the window period).

- When offering HIV PEP it is important to take into account the views of the exposed health care worker. If the exposure is significant, the exposed health care worker may wish to consider starting HIV PEP until further information is available about the source patient. In this way the option of possible benefit from prompt HIV PEP will have been kept open. Changes can be made to the HIV PEP regimen, including stopping it, once further information becomes available.

- If the HIV status of the source patient cannot be established, the exposed health care worker should have the opportunity to consider whether or not to continue HIV 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 the unknown long-term effects of taking HIV PEP drugs.

- The relative risk of transmission may be increased considerably if the source patient has a high plasma viral load. The absolute risk is difficult to determine from plasma viral load alone due to differences in viral load between body compartments. If the source patient is known to have an undetectable HIV viral load (<200 copies HIV RNA/mL) HIV PEP is not recommended (7, 9).
- If the source is HIV positive, has been on ART for 6 months with good adherence, and has an undetectable viral load – HIV PEP is not indicated following any type of exposure

- The use of HIV PEP drugs in pregnancy is discussed in Appendix B.

What to prescribe for HIV PEP

- The following regimen for HIV PEP is recommended by BASHH in its latest guidance (9) published 2021:
  One Emtricitabine/Tenofivir tablet (245 mg tenofovir disoproxil (as fumarate) and 200 mg emtricitabine (FTC)) once a day
  PLUS
  Two raltegravir tablets 600 mg once a day

- The duration of the course of HIV PEP is **28 days.**

6.6 Management of health care workers occupationally exposed to HIV: further considerations, including follow-up

- Occupational exposure to known or suspected HIV-infected materials is stressful for health care workers and, for some, extremely so (5).

- HIV PEP is most likely to be effective when initiated as soon as possible (ideally within an hour, preferably within 24 hours , and continued for 28 days. It should be noted that the evidence base on which these conclusions are based is limited. HIV PEP should be commenced as soon as possible after exposure, allowing for careful risk assessment. HIV PEP should not be initiated beyond 72 hours post-exposure (9).

- Following exposures for which HIV PEP is considered appropriate, health care workers should be given time to discuss the balance of risks in their particular situation. They should be informed that knowledge about the efficacy and toxicity of drugs used for HIV PEP is limited. It is important that the health care worker's own views about HIV PEP are taken into account. An information sheet for health care workers and questions and answers about HIV PEP is at appendix D.

- Evaluation of the health care worker should include medical history and also pre-existing risk factors for HIV infection in the health care worker. Details of any existing medication should be established. Antiretroviral medications may interact with some prescription and non-prescription drugs. Females should be asked specifically about the possibility of pregnancy (see Appendix B). All exposed health care workers should be asked to provide a baseline blood sample ('serum save') for storage.

- The following baseline tests are advised for the affected healthcare worker – 'serum save', creatinine, ALT, HIV-1 Ag/Ab, hepatitis C antibody, and a pregnancy test in all women of childbearing age considering HIV PEP (9)

- HIV PEP should normally be continued for 4 weeks. The drugs used may need to be modified if side effects are encountered.

- Follow-up on a weekly basis is likely to help improve adherence. Any need for sickness absence in a health care worker associated with side effects of HIV PEP drugs following

an occupational exposure should preferably not contribute to that individual's sickness absence record for monitoring and absence control purposes.

- All health care workers occupationally exposed to HIV should have follow-up, post-exposure testing and medical evaluation whether or not they have received HIV PEP. In addition, they should be encouraged to seek medical advice about any acute illness that occurs during the follow-up period. Most people infected with HIV experience a short (one to two weeks) flu-like illness (seroconversion illness) characterised by fever, sore throat, rash, myalgia, fatigue, malaise and/or lymphadenopathy, typically occurring two to six weeks after exposure.

- There has only been one documented case of HIV seroconversion following occupational exposure in a UK health care worker since the introduction of combination HIV PEP in the 1990s (3). No cases of delayed seroconversion (beyond 12 weeks from exposure) have been reported worldwide since the introduction of HIV PEP.

- Follow up HIV testing (10). The window period for fourth generation laboratory serological HIV testing is 45 days (this has been revised in light of published evidence). The British HIV Association/British Association for Sexual Health and HIV/British Infection Association Adult HIV Testing Guidelines 2020 advise a final HIV test a minimum of 45 days after the course of HIV PEP is completed, ie a minimum of 73 days (10.5 weeks) after the exposure (10). The test is for HIV-1/2 Ag/Ab. The window period is defined as the time interval between exposure to infection and accurate detection of that infection.. Longer follow up with additional HIV antibody testing may be needed in certain situations, for example if the exposed worker is immunocompromised, experiences an illness compatible with an acute retroviral syndrome (regardless of the interval since exposure), or when the source patient is also infected with hepatitis C.

- Plasma RNA PCR testing has no role to play in routine follow up of occupational exposure to HIV. The test has a relatively high rate of false positive results and a low positive predictive value when used to detect occupational transmission of HIV.

- Pending follow-up, and in the absence of seroconversion, health care workers who have been exposed to HIV occupationally do not need to modify their working practices, for example avoidance of exposure-prone procedures. 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 be high enough to justify taking HIV PEP and to engage in safer sex but remote enough not to warrant modification of work. This is because the risk to patients from an occupationally exposed health care worker is the product of the low risk of the health care worker becoming infected multiplied by the very low risk of onward transmission to the patient through exposure-prone procedures.

6.7 Making HIV PEP available: immediate access

- It is recommended that, for optimal efficacy, HIV PEP should be commenced as soon as possible after exposure, allowing for careful risk assessment. HIV PEP should not be initiated beyond 72 hours post-exposure (9). There may be circumstances where it is

appropriate that the exposed worker is offered the initial dose immediately, pending fuller discussion and risk assessment.

- Packs of the recommended drugs should be kept in readily accessible places, including the Occupational Health department, ED, UCC, Integrated Sexual Health and Pharmacy. Each pack should contain a minimum 3-day course of the drugs, sufficient to cover weekends and bank holidays. Arrangements will need to be in place to ensure that packs are stored appropriately and that the drugs have not passed their expiry date.

- In view of the need for prompt treatment and the serious consequences of HIV seroconversion, significant occupational exposure to known or possible sources of HIV constitutes a medical emergency. Occupational Health has limited OH Doctor cover, and in the absence of OH Doctor availability OH nursing staff will seek advice from Integrated Sexual Health or ED/UCC when PEP may be indicated. Outside normal working hours, ED/UCC assumes responsibility for assessment of occupational exposure and providing HIV PEP. As the first point of contact for any such exposure, whether or not this arises in the hospital, there is a need for ED/UCC triage nurses and ED/UCC junior medical staff to give appropriate priority to potential HIV PEP candidates who attend

SUMMARY

- This policy is based on the British Association for Sexual Health and HIV UK Guideline for the use of HIV post exposure prophylaxis which was published in 2021 and updated on 16 April 2021 (9) and which supersedes guidance from the UK Chief Medical Officer's Expert Advisory Group on AIDS (EAGA) published in September 2008 (1).

- The risk of acquiring HIV infection following occupational exposure in a health care setting is very low. The use of HIV post-exposure prophylaxis (PEP) may further reduce the risk.

- HIV PEP should be recommended to health care workers if they have had a **significant occupational exposure** to **blood or another high-risk body fluid** from a patient or other source **known to be HIV infected**, or considered to be **at high risk of HIV infection**, and where the HIV+ patient has been on ART for less than six months and where the viral load has not been suppressed for six months

- HIV PEP is not indicated where source patient is HIV+, but on ART >6 months, with an undetectable viral load (<200 copies/mL) and good adherence; following a splash incident if undetectable viral load; if low or no risk of exposure (for example intact skin); if index case untested and in a low risk group; following community needlestick exposure where source not identified; following a human bite (unless saliva visibly blood stained, HIV viral load >3 log copies, and if the injury is a severe deep bite injury.

- A **significant occupational exposure** is one with the potential to transmit HIV. There are three exposure routes with the potential to transmit HIV: (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.

- All source patients should be approached and asked to consent to testing for HIV antibody, hepatitis B surface antigen and hepatitis C antibody. HIV PEP should not be offered where testing has shown that the source patient is HIV negative, or if risk assessment has concluded that HIV infection of the source is unlikely.

- The following regimen for HIV PEP is recommended by the British Association for Sexual Health and HIV UK Guideline for the use of HIV post exposure prophylaxis which was published in 2021 and updated on 16 April 2021 (9) and which supersedes guidance from the UK Chief Medical Officer's Expert Advisory Group on AIDS (EAGA) published in September 2008 (1). :
  One Emtricitabine/Tenofivirtablet (245 mg tenofovir disoproxil (as fumarate) and 200 mg emtricitabine (FTC)) once a day
  PLUS
  Two raltegravir tablets 600 mg once daily

- The duration of the course of HIV PEP is **28 days.**

- HIV PEP should be commenced as soon as possible following exposure (ideally within an hour and preferably within 24 hours). Health care workers should immediately contact the Occupational Health department during normal working hours and attend the Emergency Department (ED) or Urgent Care Centre (UCC) out of hours.

- A flow chart surmises the procedure to be followed by management and health care workers following blood body fluid exposure incident (Appendix E)

7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
Reporting of sharps/body fluid exposure injuries	H&S Manager	Audit via incident reporting system (Datix system)	Annually	IPCC (formal report from safer sharps group)
Reporting of sharps/body fluid exposure injuries to OH	Head of Occupational Health/Lead Nurse	Audit via OH database (OPAS system)	Monthly	Safer sharps group

8.0 TRAINING AND IMPLEMENTATION

Awareness training covered at induction and mandatory training

9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at Appendix F
- This document is not subject to an Environmental Impact Assessment

10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

Evidence Base:

(1) Department of Health. HIV Post-exposure prophylaxis: Guidance from the UK Chief Medical Officers' Expert Advisory Group on AIDS. Department of Health; 2008

(2) Cardo D, Culver DH, Ciesielski CA, Srivastava PU, Marcus R, Abiteboul D, et al. A case control study of HIV seroconversion in health care workers after percutaneous exposure. N Engl J Med 1997;337:1485–90

(3) Hawkins DA, Asboe D, Barlow K, Evans B. Seroconversion to HIV-1 following a needlestick injury despite combination post-exposure prophylaxis. J Infect 2001; 43: 12–15

(4) Chief Medical Officer. Improving the detection and diagnosis of HIV in non-HIV specialties including primary care (CEM/CMO/2007/19)

(5) Worthington MG, Ross JJ, Bergeron EK. Post-traumatic stress disorder after occupational HIV exposure: two cases and a literature review. Infect Control Hosp Epidemiol 2006; 27: 215–7

(6) Expert Advisory Group on AIDS. Change to recommended regimen for post-exposure prophylaxis (PEP). EAGA secretariat September 2014 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/351633/Change_to_recommended_regimen_for_PEP_starter_pack_final.pdf

(7) Expert Advisory Group on AIDS. Updated recommendations for HIV post-exposure prophylaxis (PEP) following occupational exposure to a source with an undetectable viral load. EAGA secretariat December 2013 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/275060/EAGA_advice_on_PEP_after_exposure_to_UD_source_Dec13.pdf

(8) British Association of Sexual Health and HIV (BASHH) and Expert Advisory Group on AIDS (EAGA) joint position statement on the time period for HIV testing. EAGA secretariat October 2014 https://www.gov.uk/government/publications/time-period-for-hiv-testing-position-statement

(9) British Association for Sexual Health and HIV UK Guideline for the use of HIV post exposure prophylaxis (2021) updated 16 April 2021
https://www.bashhguidelines.org/media/1269/pep-2021.pdf

(10) British HIV Association/British Association for Sexual Health and HIV/British Infection Association Adult HIV Testing Guidelines 2020

Related SFHFT Documents:

- Sharps & Needlestick Policy (Including disposal and any bodily fluid exposures or inoculation injury)
- Personal Protective Equipment ICP: 9
- Isolation Policy ICP: 31
- Decontamination and Disinfection ICP: 40
- Safe Linen Disposal ICP: 10
- Blood and body fluids spillage policy ICP: 4
- Infectious Outbreak/ Incident including major outbreak IPC 27

- Trust Waste Management Policy
- SFH Mental Capacity Act Policy
- Policy for the care of sharps in the perioperative environments

11.0 KEYWORDS

Needle stick; HIV; Hepatitis B C; blood borne agents; accidental inoculation; contamination; eyes; mucous membrane; broken skin; bites; scratches

12.0 APPENDICES

Appendix A – Body fluids and materials which may pose a risk of HIV transmission if significant occupational exposure occurs
Appendix B – HIV PEP in pregnancy
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Appendix A

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

Body fluids which pose a risk of HIV transmission:

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 contamination with blood)
Semen
Synovial fluid
Unfixed human tissues and organs
Vaginal secretions
Any other body fluid if visibly bloodstained

Body fluids felt not to be associated with a risk of HIV transmission unless visibly blood-stained:

Urine
Vomit
Saliva
Faeces
Sweat
Tears

Appendix B

HIV PEP in pregnancy

Pregnancy does not preclude the use of HIV PEP. Expert advice should always be sought if HIV PEP is 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 HIV PEP.

The British HIV Association has published guidelines for prescribing antiretroviral therapy in pregnancy. 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.

A pregnant health care worker who has experienced an occupational 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 decision about the use of HIV PEP.

Appendix C

Risk that source patient is HIV positive

Based on PHE 2018 data and table 1 https://www.bashhguidelines.org/media/1269/pep-2021.pdf (9)

Community group	**Rate with detectable HIV virus* England**	
Homosexual/bisexual men		
London	3.2%	
UK	2.3%	
Heterosexual	**Male**	**Female**
Black African	0.5%	0.9%0.2%
Non black African	0.02%	0.01%
Injecting drug users		
England	0.7%	

- Viral load undetectable is defined as <200 copies/mL, above this is detectable and 'transmissible'

Appendix D

Occupational exposure to HIV – Summary Information

Document for Exposed Health Care Workers and Those Who Manage Incidents and Questions and Answers about HIV PEP

The risk of acquiring HIV infection following occupational exposure is very low. Epidemiological studies have indicated that the average risk of HIV transmission after percutaneous exposure to HIV-infected blood in health care settings is about 3 per 1,000 incidents. After a mucocutaneous exposure, the average risk is estimated at less than 1 in 1,000. There is no risk of HIV transmission where intact skin is exposed to HIV-infected blood.

If initial assessment indicates that an exposure has been significant - with the potential for HIV transmission - consideration should be given to the HIV status of the source patient. It may be possible to ascertain from the source patient or their medical records the HIV status of the source patient. Appropriate arrangements should be made to approach a source patient whose HIV status is not known and ask for their informed agreement to HIV antibody testing together with hepatitis B surface antigen and hepatitis C antibody.

HIV PEP should be recommended to health care workers if they have had a significant occupational exposure to blood or another high risk body fluid from a patient or other source either known to be HIV infected or considered to be at high risk of HIV infection. PEP should not generally 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. It is important to take into account the views of the exposed healthcare worker.

HIV PEP is most likely to be effective when started as soon as possible after exposure, allowing for careful risk assessment, and ideally within an hour. HIV PEP is not generally recommended beyond 72 hours post-exposure. There may be circumstances where it is appropriate that the exposed healthcare worker is offered the initial doses immediately, pending fuller discussion and risk assessment. The duration of HIV PEP is 28 days. The evidence on which these recommendations are based is limited.

All exposed health care workers should be asked to provide a baseline blood sample for storage. All exposed healthcare workers should be asked to contact the occupational health department as soon as possible on the next working day. The following factors in the healthcare worker should be taken into account when prescribing HIV PEP – pregnancy, pre-existing medical conditions, concurrent medication and the possibility of drug resistance. In all these circumstances expert advice should be sought.

Questions and Answers for Healthcare Workers about HIV PEP

What is my risk of becoming infected with HIV following occupational exposure?

Answer. The risk of developing HIV infection after a single exposure from a known HIV positive source is very **low**. Studies have indicated that the risk of HIV transmission after percutaneous (through the skin) exposure to HIV infected blood in health care settings is no more than 3 per 1,000 incidents and likely to be much less than this. After a mucocutaneous exposure (blood splash directly into eyes or mouth) the average risk is estimated at less than 1 in 1,000. There is no risk of HIV transmission where intact skin is exposed to HIV-infected blood.

Four factors are associated with an increased risk of occupationally acquired HIV infection:
Deep injury
Visible blood on the device which caused the injury
Injury with a hollow-bore needle which has been placed in a source patient's artery or vein
High viral load in source patient, for example terminal HIV-related illness

Following occupational exposure to HIV only five cases of HIV seroconversion in UK health care workers have been documented; four occurred in or before 1993, only one of whom received post-exposure prophylaxis (PEP) (zidovudine monotherapy). The most recent case was in 1999, when seroconversion occurred despite combination PEP.

Will post-exposure prophylaxis prevent me from becoming infected with HIV?

Answer. 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 of occupationally acquired HIV infection. This means that HIV PEP may change the average risk of HIV seroconversion after a percutaneous exposure from about 30 per 10,000 incidents (0.003) to approximately 6 per 10,000 incidents (0.0006).

How soon after the injury should I start taking HIV PEP?

Answer. HIV PEP should be recommended to health care workers if they have had a significant occupational exposure to blood or another high-risk body fluid 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. HIV PEP is most likely to be effective when started as soon as possible (within hours, and certainly within 48-72 hours of exposure) and continued for 28 days. The evidence on which these recommendations are based is limited. Therefore HIV PEP should be commenced as soon as possible after exposure, allowing time for risk assessment, and ideally within an hour. HIV PEP is not generally recommended beyond 72 hours post-exposure.

What is HIV PEP?

Answer. The following 28 day regimen is recommended (6):
One Emtricitabine/Tenofivirtablet (245 mg tenofovir and 200 mg emtricitabine) once a day
PLUS
Two raltegravir tablets 600 mg once a day

Is it safe to take PEP during pregnancy?

Answer. Pregnancy does not preclude the use of HIV PEP. Expert advice should always be sought if HIV PEP is considered to be indicated for a pregnant health care worker. The British HIV Association has published guidelines for prescribing antiretroviral therapy in pregnancy. There has been no indication of particular problems for the babies of HIV-infected women who have become pregnant while already on antiretroviral medication. There is limited experience of the use in pregnancy of some of the newer anti HIV drugs.

What are the side effects of HIV PEP?

Answer. All of the antiretroviral agents have been associated with some side effects. Many of these can be managed symptomatically. Side effects of Emtricitabine/Tenofivir include gastrointestinal symptoms (nausea and diarrhoea) as well as dizziness and headache.

Are there any medications that I am currently taking that interact with PEP?

Answer. Antiretroviral medications may interact with other prescription or non-prescription drugs. You should tell the doctor who prescribes HIV PEP for you of any medication you are currently taking. The doctor will be able to check on potential interactions.

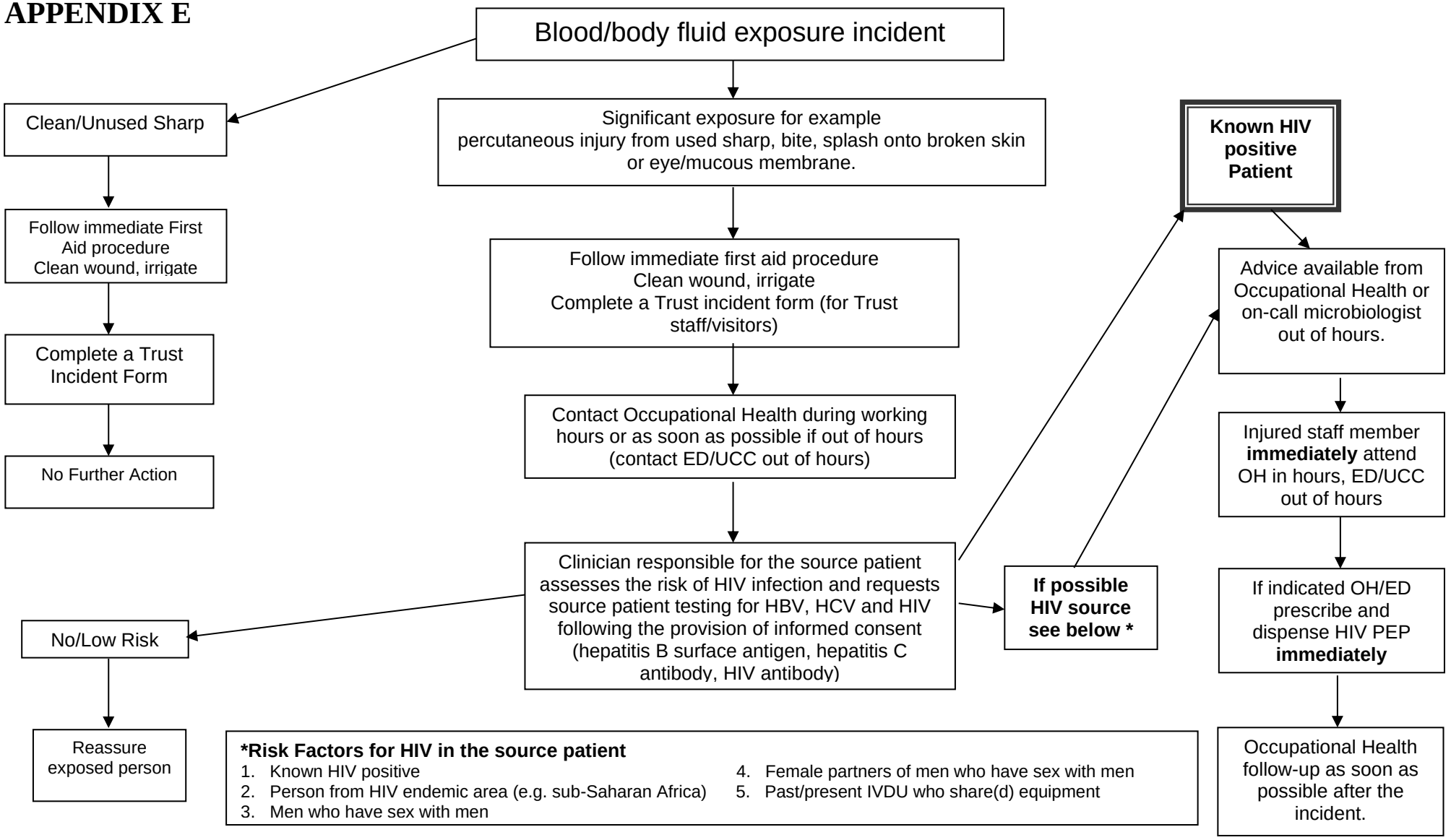
What blood tests do I need to have?

Answer. Blood is taken immediately for storage in the laboratory. This is called a serum save and will **not** be tested without your consent. This is a baseline sample so that you can show later, in the very unlikely event of your developing HIV or any other illness, that you were not infected at the time of the incident. The recently published Department of Health guidance is now recommending one follow up blood test for HIV antibodies 45 days following the majority of exposure incidents. For those who complete a 28 day course of HIV PEP the recommended testing is undertaken 45 days following completion of the course, or 73 days (10.5 weeks) following the exposure incident.

Do I need to take any infection control precautions myself in the follow-up period?

Answer. In the follow up period healthcare 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. The guidance recommends, however, reinforcing the importance of simple infection control measures, safer sex and avoiding blood donation during the follow up period.

APPENDIX E


Blood/body fluid exposure incident
Clean/Unused Sharp
Follow immediate First Aid procedure Clean wound, irrigate
Complete a Trust Incident Form
No Further Action
Significant exposure for example percutaneous injury from used sharp, bite, splash onto broken skin or eye/mucous membrane.
Follow immediate first aid procedure Clean wound, irrigate Complete a Trust incident form (for Trust staff/visitors)
Contact Occupational Health during working hours or as soon as possible if out of hours (contact ED/UCC out of hours)
Clinician responsible for the source patient assesses the risk of HIV infection and requests source patient testing for HBV, HCV and HIV following the provision of informed consent (hepatitis B surface antigen, hepatitis C antibody, HIV antibody)
No/Low Risk
Reassure exposed person
If possible HIV source see below *
Known HIV positive Patient
Advice available from Occupational Health or on-call microbiologist out of hours.
Injured staff member immediately attend OH in hours, ED/UCC out of hours
If indicated OH/ED prescribe and dispense HIV PEP immediately
Occupational Health follow-up as soon as possible after the incident.
*Risk Factors for HIV in the source patient
1. Known HIV positive
2. Person from HIV endemic area (e.g. sub-Saharan Africa)
3. Men who have sex with men
4. Female partners of men who have sex with men
5. Past/present IVDU who share(d) equipment

APPENDIX F- EQUALITY IMPACT ASSESSMENT FORM (EQIA)

Name of service/policy/procedure being reviewed: HIV post-exposure prophylaxis (PEP) policy following occupational exposure to HIV in the health care setting			
New or existing service/policy/procedure: Existing			
Date of Assessment: 16 August 2021			
For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)			
Protected Characteristic	**a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?**	**b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?**	**c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality**
The area of policy or its implementation being assessed:			
Race and Ethnicity	The policy when applied correctly gives no potential for disadvantage	Clearly identifies roles and responsibilities.	None
Gender	The policy when applied correctly gives no potential for disadvantage	Clearly identifies roles and responsibilities.	None
Age	The policy when applied correctly gives no potential for disadvantage	Clearly identifies roles and responsibilities.	None
Religion	The policy when applied correctly gives no potential for disadvantage	Clearly identifies roles and responsibilities.	None
Disability	The policy when applied correctly gives no potential for disadvantage	Clearly identifies roles and responsibilities.	None
Sexuality	The policy when applied correctly gives no potential for disadvantage	Clearly identifies roles and responsibilities.	None
Pregnancy and Maternity	The policy when applied correctly gives no potential for disadvantage	Clearly identifies roles and responsibilities.	None

Gender Reassignment	The policy when applied correctly gives no potential for disadvantage	Clearly identifies roles and responsibilities.	None
Marriage and Civil Partnership	The policy when applied correctly gives no potential for disadvantage	Clearly identifies roles and responsibilities.	None
Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation)	The policy when applied correctly gives no potential for disadvantage	Clearly identifies roles and responsibilities.	None

What consultation with protected characteristic groups including patient groups have you carried out?

- Consultation with Infection Prevention and Control Committee Members

What data or information did you use in support of this EqIA?

- Information from within the policy

As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?

- No

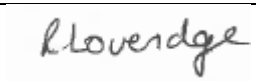
Level of impact

From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (click here), please indicate the perceived level of impact:

Low level of impact

For high or medium levels of impact, please forward a copy of this form to the HR Secretaries for inclusion at the next Diversity and Inclusivity meeting.

Name of Responsible Person undertaking this assessment: Rebecca Loveridge

Signature: 

Date: 16 August 2021