University Hospitals of Derby and Burton NHS Foundation Trust

TRUST POLICY AND PROCEDURES FOR THE MANAGEMENT OF INOCULATION INCIDENTS

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	1	Sept 2008	J Fletcher	To meet NHSLA Standards
	1.2	Oct 2008	P Twine	Amendments
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	2.1	Sept 2010	Gill Ogden	Monitoring section updated
	2.2	June 2012	H Forrest	Minor amendment to Appendix 4
	2.3	Dec 2013	D Sherwood-Jones	Minor amendment to 5.8 Bullet point one.
	2.5	Aug 2014		Amendments
	2.6	Mar 2015	Occ Health/ Infection Control	PEP update. Amend appendix 1
	3	Jan18	Occupational Health/Infection Control	To update and Amend
	3.1	Jan 2020	Occupational Health/Infection Control	Update and Amend following Trust merger
Intended Recipients: All clinical and medical staff, Associate Directors, Service Managers, Heads of Nursing, Quality Improvement Leads, Senior Matrons, Occupational Health Department				
Training and Dissemination: Infection control training (including inoculation incident procedure) is a compulsory requirement for all staff and is part of the Trusts induction program. Each member of staff, identified in the training needs analysis will have an update every two years. Dissemination via Trust Intranet. Internal Occupational Health, GUM and ED Training on update on policy.				

To be read in conjunction with: Trust Policy and Procedures for Infection Control, Trust Safe management and handling of sharps policy, Trust Policy for the Assessment and Management of Risk, Trust Policy and Procedure for Incident Reporting, Analysing, Investigating and Learning, Trust Policy for Decontamination.	
In consultation with and Date: Consultant Microbiologists, Occupational Health, Antimicrobial Pharmacist, Infection Control Committee, Facilities Operations Group, Quality Assurance Committee, Emergency Department, Medical Advisory Committee, Sharps Safety Committee.	
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Contact for Review	Occupational Health / Health and Safety/ Infection Prevention and Control Lead
Approving Executive Signature	 Executive Chief People Officer

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TRUST POLICY AND PROCEDURES FOR THE MANAGEMENT OF INOCULATION INCIDENTS

1 Introduction

This policy provides a framework for the effective management of incidents where health care workers have been potentially exposed to blood borne viruses in the course of their work. This applies to all employees and workers within the Trust, including students, agency, and locum staff, in the event of a needle stick/sharps or other exposure injury which could put them at risk of infection and acquiring a blood borne virus (BBV) - Hepatitis B (HBV), Hepatitis C (HCV) or Human Immunodeficiency virus (HIV). The policy can also be used by the Emergency Department (ED) as a guide to advise and support when a member of the public reports a needle stick /sharps injury or contamination with body fluids.

Needle stick or sharps injuries occur when a needle or other sharp instrument accidentally or inadvertently penetrates or breaks the skin (a percutaneous injury). If the needle or sharp instrument is contaminated with blood or other body fluid, there is the potential for transmission of infection, and when this occurs at work, the term occupational exposure (to blood, body fluid or blood-borne infection) is used.

When blood or other body fluid splashes into the eyes, nose or mouth the exposure is referred to as mucocutaneous whereby the mucous membranes have been contaminated. Other potential routes of exposure to blood or other body fluids include bites, scratches and via broken, non-intact skin.

Exposure to blood and body fluids remains a major hazard in the NHS, with needle stick and other sharps injuries being one of highest causes of injury to healthcare workers. This can result in potential transmission of blood borne viruses, anxiety to both patients/ Health Care Workers and costs incurred by the NHS

2 Purpose and Outcomes

The purpose of this policy is to ensure the Trust complies with its legal responsibilities under the Health & Safety at Work Act 1974 and the Control of Substances Hazardous to Health Regulations (COSHH 2002) with regard to the management of exposure to BBV's and post exposure processes. The Trust has a duty of care to ensure that anyone who is in receipt of an inoculation incident is suitably and efficiently assessed and appropriately managed, with the need to ensure that the risk from an inoculation incident is reduced to as low as reasonably practicable. Other aspects include the proper use of protective equipment and regular monitoring of exposure.

The Health & Social Care Act 2008-Code Of Practice for the NHS for prevention and control of healthcare associated infections (revised January 2015) stipulates that NHS bodies must in relation to preventing and controlling the risk of healthcare infections, have in place appropriate core policies and procedures for the management of accidental exposure to blood borne viruses. This includes the safe handling, disposal and storage of sharps.

This policy describes the process for assessing, managing, and reducing the risk associated with Inoculation Incidents among Trust healthcare workers and incorporates the updated UK Guidelines for the Use of HIV Post Exposure Prophylaxis (2021). It also includes the relevant operational and clinical governance arrangements to deal with such incidents.

The Health & Safety Sharps Instruments in Healthcare Regulations (2013) state that if an employee sustains any such occupational exposure incident, which has the potential to cause infection, immediate steps must be taken to ensure they receive an assessment and advice from an appropriate health professional. Within the Trust, this should be carried out by a trained practitioner in the Occupational Health Department (OHD) during working hours or Emergency Department (ED) if out of hours. Risk assessment of the incident, consent for testing of the source and appropriate management of the healthcare worker (HCW) are essential for protecting HCWs from HBV, HCV and HIV once an occupational injury has occurred. Individuals should be offered testing, immunisation and post exposure prophylaxis (PEP) when required with minimal delay.

Assessment of affected workers by appropriate professionals, including the BBV testing of the Source Patient/ individual must take place without delay to ensure:

- Effective treatment can be given where required.
- The affected worker is able to return to work as early as possible.
- The psychological burden and concerns about the possibility of contracting a BBV infection is minimised

All staff should be aware of local arrangements for advice and management of occupational exposure to blood borne viruses (BBVs).
This includes:

- Reporting arrangements in relation to Inoculation Incidents
- The procedures to follow should a person sustain an Inoculation Injury or other injury which could result in exposure to or transmission of a blood borne virus
- The immediate management of an Inoculation Incident (including Post Exposure Prophylaxis)
- The support available to those who are involved or affected
- Training that will be provided in accordance with the Trust Training Needs Analysis
- The process for monitoring compliance
- A process whereby deficiencies are identified, recommendations and action plans are developed, and changes implemented accordingly

3 Definitions Used

Inoculation Incident: An Inoculation incident is taken to have occurred when blood or body fluids from an individual is inoculated through broken skin or is in direct contact with the mucous membranes of the eyes, nose or mouth. Most inoculation incidents are caused by needle sticks, sharp instruments, splashes, bites or scratches.

Contaminated Sharp Injury: Any injury which breaks the skin, caused by any sharp needle/scalpel/ razor, or other instrument that has been used on another person. Therefore, is contaminated with blood or other high risk body fluids.

Blood Borne Virus (BBV): These are pathogenic micro-organisms that may be present in human blood or other body fluids and materials. These viruses can infect and cause disease in persons who are exposed. These pathogens include hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

Source Individual: Any individual, living or dead, whose blood or other potentially infected body material, may be a source of the blood or body fluid that the HCW is exposed to.

Recipient: Any individual who has been put at risk of contracting a blood borne virus following an inoculation incident and exposure to blood or body fluids.

Responsible Clinical Team: This is the clinical team responsible for the medical care of the source patient/ individual. In the case of an inoculation incident, the Responsible Clinician should be a Doctor looking after the patient at the time of the incident or if appropriate the Senior Nurse in charge or Senior Nurse involved in the patients care

High Risk Body Fluids: Body fluids and tissues potentially containing BBV

The risk of occupational blood borne virus transmission arises from the possibility of workers becoming exposed to blood or more rarely the following materials/ fluid from an infected patient:

- Amniotic fluid

- Breast milk
- Blood-stained saliva, particularly in dental procedures
- Cerebrospinal fluid
- Fluid from burns or skin lesions
- Peritoneal fluid
- Pericardial fluid
- Pleural fluid
- Semen
- Synovial fluid
- Unfixed tissues or organs
- Vaginal secretions
- Other visibly bloodstained fluids

There is no evidence that BBV transmission can occur via intact skin or by faeco-oral contamination

High Risk Source: A high risk source is either:

- known to be blood borne virus positive.
- in a risk category for being blood borne virus positive such as AIDS defining illness, a man who has sex with men, past or current intravenous drug user, person from a high prevalence area for BBV, particularly if had invasive procedures or blood transfusions where blood screening or infection control standards cannot be guaranteed. If received blood transfusion in UK before full screening was introduced (1992)
- source unknown but the sharp involved probably used in one of these categories above.
- clinical suspicion is of a high-risk source.

Low Risk Body Fluids: These include urine, vomit, saliva (except in association with dentistry or poor dentition e.g. with bleeding gums), faeces, tears, sweat and sputum (except when these body fluids are blood stained).

Percutaneous Exposure: Where the skin has been broken by a contaminated 'sharp'. A 'sharp' is defined as a needle, sharps instrument/ blade/ razor or other sharp object which includes human bite or deep scratch where the skin has been broken. In addition, non-intact skin exposed to blood or body fluid.

The average estimated risk of infection following percutaneous exposure is:

- 1 in 3 if source patient is HBV positive.
- 1 in 30 if source patient is HCV positive.
- 1 in 300 if source patient is HIV positive.

These figures can vary depending on factors such as whether the Source Patient has current infection/ viral load and either has in the past or is currently receiving treatment. They do however give a comparison between the BBV

Mucocutaneous Exposure: Where the mucous membranes (nose, mouth or eyes) have been contaminated with blood or body fluid.

Post Exposure Prophylaxis (PEP): Treatment given to an individual after the inoculation incident which reduces the risk of sero-conversion following a high-risk exposure to HIV.

4 Inoculation incident:

Factors associated with an increased risk of occupationally acquired BBV infection:

- Deep injury was sustained.
- The sharp/ device was visibly contaminated with the patient's blood.
- The sharp/ device placement was in a vein/ artery.
- Injury sustained from a contaminated/ used hollow needle.
- Splash of bodily fluid that contains blood or is visibly blood stained to mucosal surfaces (mouth, nose, eyes)
- Risk of HIV acquisition from a mucocutaneous splash injury (e.g eye, mouth, nose) is considerably lower than a percutaneous sharps injury (estimated 1 in 1000 risk compared to percutaneous 'sharps' injury 1 in 333, 0.3%)
- The risk of Hepatitis B transmission is increased if the source patient has current infection and is HBeAg positive.
- A high plasma viral load in the source patient/ individual is associated with an increased risk of HIV and Hepatitis C transmission.
- Bite from a patient with visible bleeding in the mouth that causes bleeding in the exposed worker.
- A non-intact skin (e.g dermatitis, chapped skin, abrasion, or open wound) exposure to blood, visibly blood-stained fluid, or other potentially infectious material

5 Key Responsibilities / Duties

5.1 Director of infection prevention and control / Deputy

- Implementation of policy in the Trust and reporting to Trust board

5.2 Sharps Safety Management Group

- Act as the strategic focus for sharps safety issues across the Trust and aim to ensure legal compliance of all relevant Health & Safety legislation requirements.
- Chaired by the Head of Health & Safety and will report into the Strategic Health Safety & Wellbeing Group, working closely and in conjunction with Medical Devices
- Review data of inoculations incidents within the Trust to identify trends and lessons that can be learnt. To share key learning within the Trust and action suitable recommendations, where possible preventing similar incidents
- Keep up to date with development in practice and new sharps devices.
- Will receive a six-monthly report on Inoculation Injuries from the Occupational Health Department.

5.3 The Trust Risk Management Department

- Will ensure that Occupational Health and Health and Safety receive all Datix notifications relating to Inoculation Injuries

5.4 The Infection Control Team

- Will advise the Trust and staff on which products and resources to be made available for staff use to prevent inoculation incidents.

- Will provide and support Inoculation Incident Training at both Trust Induction and mandatory Infection Control Training.

- Will undertake annual audit of safe sharps practice as part of the Infection Control Audit Program.
- Will approve the policy for Infection Prevention & Control

5.5 The Occupational Health Department

- Takes overall lead on managing occupational BBV exposure incidents.

- Will liaise with the Health and Safety Department when Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) is applicable. Health and Safety should be informed of RIDDOR reportable incidents at DHFT.healthandsafety@nhs.net.

  This would be when an incident involves a positive BBV patient and/ or if a staff member acquires a BBV as a result of an inoculation incident.
  A contamination injury where the Source patient is positive for Group 3 or 4 infections as defined by the Advisory Committee on Dangerous Pathogens is reportable under RIDDOR 2013. This includes all the Blood Borne Viruses. The Trust Health and Safety Manager/ Team will take responsibility for reporting to the Health and Safety Executive (HSE) incidents that fulfil the RIDDOR criteria.

- Provides advice to/ manages affected workers immediately following BBV exposure incidents that occur during OHD working hours.

- Liaises with GU clinic Specialists if initiation/ continuation of PEP for HIV needs to be considered and/or for appropriate support and advice of individual cases.

- Responsible for follow up of the Source Patient results solely for the purposes of ongoing management of the recipient (staff). Provides rapid and continuous review for all affected workers with significant exposure incidents.

- Arranges follow up testing of affected health care worker/staff as indicated, until BBV seroconversion (infection) has been excluded. In the rare event of BBV diagnosis, instigate appropriate follow up and health surveillance of the recipient (staff) including onward referral to Specialist Teams if appropriate (such as Hepatology). Review of fitness for work if required.

- Occupational Health will report to Blood Born Viruses Unit, UK Health Security Agency (UKHSA) inoculation incidents where a Source Patient is known or subsequently found to be infected with a BBV. Staff cases where PEP for HIV has been commenced, will also be reported using the relevant systems to UKHSA, for National Health Surveillance

- Will provide an ongoing immunisation program for Hepatitis B vaccinations in line with current guidance. Administer Hep B immunoglobulin as indicated.

- Will submit 6 monthly reports of Inoculation Incidents to the Trust Sharps Safety Management Group

- Will provide support to managers and the affected staff /recipient on the risk assessment, following needlestick or exposure incident.

- Will provide initial and on-going support and information to employees following Inoculation injuries. Offer and action counselling where indicated.

- Provide advice to Managers about an employee's fitness to work if required.

- Recording of inoculation incidents and with respect to recipient (staff) outcome

- Review and update this policy in line with national guidance.

5.6 Consultant Microbiologist/ Virology / Genitourinary Medicine (GUM) Consultant

- Will give expert advice on the clinical management of incidents on an individual basis.
- Consultant Microbiologist will, where necessary, authorise the supply of Hepatitis B Immunoglobulin from the supply maintained in the Pharmacy / Microbiology Department.
- The GUM Physician will advise on and provide initial & ongoing PEP medication for high-risk exposure incidents or known exposure to HIV positive source when clinically indicated in hours (8.30-4pm).

5.7 The Emergency Department

- Will support the Trust in the assessment and management of reported Inoculation Incidents of employees and other staff undertaking work activities within the Trust, outside the working hours of Occupational Health
- Will liaise with the Consultant Microbiologist and the local Genitourinary Medicine Department for advice on management and follow up, out of the working hours of Occupational Health. In hours to contact Occupational Health
- Will offer initial counselling and support to employees relating to Inoculation Incidents outside the working hours of Occupational Health.
- Will prescribe and dispense PEP for HIV when clinically indicated out of the working hours of Occupational Health or on the request of Occupational Health in working hours.
- Arrange for bloods to be taken from the injured health care worker for storage. If commencing PEP baseline bloods to be taken (as per assessment form Appendix 5)
- Administer Hep B vaccine / Hep B immunoglobulin as required, based on risk assessment.
- Will advise affected staff to contact Occupational Health on the next working day for further assessment/ management and to arrange follow up.
- Will use the appropriate assessment tools and documents embedded within this policy for the assessment and management of the staff/ individual that has received an Inoculation Incident. The proforma will facilitate a structured assessment to establish significance of exposure/ risk, indication to commence HIV-PEP and Hep B vaccination status.

5.8 Associate Directors / Health and Safety/ Quality and Risk Leads

- Will ensure that all staff comply with the Policy and Procedures for the Management of Inoculation Incidents.
- Will receive Inoculation Incident reports, disseminate findings and take any action appropriate, in a timely manner.
- Will encourage appropriate reporting.

5.9 Managers / Matrons / Clinical Leads

- Will ensure the Policy and Procedures for the Management of Inoculation Incidents is implemented and complied within their areas of responsibility.
- Will ensure when an inoculation accident occurs that a risk assessment is carried out by the clinician caring for the patient or a senior member of the nursing team and plans are in place for source patient BBV testing with consent.
- Will ensure staff are informed and signposted to the Inoculation Incident Policy and Procedure in addition to Safe Sharps Practice as part of Staff Induction. Identify education and practice requirements.
- Will ensure that appropriate equipment including Inoculation Incident Procedure posters are. available and placed correctly in their clinical areas of responsibility, for safe systems of working.
- Identify resource issues and consider needle free systems. Ensure needle safety devices where possible.
- Will ensure that all Inoculation Incidents are reported via Datix to the Risk Management Department and that subsequent root cause analysis investigation is undertaken to ensure that learning outcomes are identified and actioned. This may include review of processes, change of practice and local auditing.
- To facilitate individual staff having access to Occupational Health/ED and staff counseling services following an incident as required
- To promote and support immunisation programs for staff within their clinical teams, to reduce risk of acquiring infections.

5.10 Individual Employees

- Are responsible for ensuring their own practice complies with this Policy and for encouraging others to do so.
- To undertake their roles in a manner that reduces the risk of sharps injury not only to themselves but to patients and colleagues. Ensure compliance to associated Trust policies of PPE and hand hygiene and Trust Safe Management of Sharps policy.
- Are responsible for attending the Occupational Health Department to undergo and complete immunisation programs as identified by Trust Risk Assessment.
- Should be aware of their immunisation history and Hepatitis immunity status (responder or non-responder)
- To report high risk incidents to Occupational Health promptly after an Inoculation Incident Occurs.
- To ensure that Managers / Matrons / Clinical Leads have been informed of the Inoculation Injury and of any near misses or unsafe systems of work that could potentially endanger themselves, colleagues or patients.

5.11 Source Patient Clinical Team

- Has a responsibility to undertake the steps in this policy necessary to support the risk assessment and clinical management of the recipient. This includes arranging Source Patient consent and taking of bloods for a BBV screen.

- Following up on the source individual (patient) blood test results, informing the Source Patient of their results and initiating clinical management / specialist referral if appropriate

6 Prevention and Management of Inoculation Incidents

6.1 Prevention

- Prevention of sharps injuries by following the Trust Safe Management of Sharps Policy
- Ensure any cuts or breaks in the skin are covered with waterproof dressings.
- Wear PPE as risk assessed for any contact or risk of splashes with blood or body fluids (follow Trust Hand hygiene and PPE policy

Actions to be taken following an injury

6.2 First Aid

- Do not suck the wound. Gently encourage free bleeding of puncture wounds. Squeezing the wound to express blood is not recommended.
- Immediately wash the site of exposure (e.g. wound or non-intact skin) liberally with soap and water **without** scrubbing. Small wounds and punctures may also be cleaned with alcohol-based hand hygiene solution/ sanitizer since alcohol is virucidal to HIV, Hepatitis B virus (HBV) and Hepatitis C (HCV)
- Dry area and apply waterproof dressing.
- Exposed mucous membranes (eyes, nose, mouth), should be irrigated liberally with water. For eyes; this should be before and after removal of any contact lenses.

6.3 Report the Incident

- All incidents must be reported immediately to a senior person on duty in the area where the incident occurred. This person is responsible for liaising with the Clinical/ Medical Team and undertaking an initial risk assessment of the incident, ensuring the necessary actions are taken (see Appendix 1 and 2). Further advice on undertaking the risk assessment may be obtained by a relevant health professional from the Occupational Health Department or the Emergency Department (out of hours).

- Promptly report incident to **Occupational Health** during departmental opening hours Mon-Friday 8.30-4pm. If occurs outside of hours, attend ED if the incident is of unknown or potential/ known high risk. Risk assessment should be based on clinical details of the patient and as per information on the Assessment and immediate action poster (Appendix 1 and 2). Patient case notes should be checked. If attends ED: Occupational Health must be contacted the next opening/ working day, to inform and for discussion of assessment and any further management required, based on individual case.

6.4 Blood Specimen Collection and Testing

Source patient: following completion of the risk assessment, the senior responsible clinician caring for the patient should follow guidelines on patient consent. If consent is gained the clinician should arrange for the collection of blood in a red topped clotted blood bottle. The consent must include testing for HIV antigen/antibody, Hepatitis B Surface antigen and Hepatitis C antibody (see Appendices 6 and 7 for guidelines on seeking consent for blood borne virus testing from a source patient).

The blood forms/ Meditech V6/ Lorenzo request;

Blood samples both from the patient and injured staff should be sent off separately in <u>different</u> bags with the appropriate Microbiology/Serology form/ request:

<u>Patient form:</u> should clearly state the source patient full details (name, DOB, hospital number and ward/department). Document **'Inoculation Incident Source patient' in the clinical details section.** In brackets add the staff/ recipient details (name and DOB) and the date of the incident. It is important to request the blood borne virus tests (Hepatitis B Surface antigen/ Hep C antibody and HIV screen) that the patient has consented to. Only the tests requested on the form will be tested. If the Source Patient/ individual is already known positive for a BBV then an up-to-date viral load can be requested providing consent has been gained for this.

If the Source Patient has already been discharged at the point of consent/ collection of bloods, then the Clinical Team in charge and responsible for their care should review the case and where possible contact the patient to inform them of the incident. The risk assessment should be carried out and discussed, arranging for them to return or liaise with the GP if appropriate, for testing of blood borne viruses. The Team is responsible for informing the patient of the test results and if required, arranging further advice or treatment via an appropriate Specialist. If Source Patient testing is deemed inappropriate or not possible, then a risk assessment based on available information by the Clinical Team can be used to guide decisions on prophylaxis and follow up for the affected worker.

The consent and documentation of the incident should be recorded in the Source patient medical records. This is particularly important when there is a possibility of bleeding from the injured health care staff into the patient tissues (reverse contamination incident) when the source patient will also then be considered a potential recipient. Circumstances that could allow the transmission of BBV from a health care worker to a patient include:

- Laceration of a HCW's hand where the patients open tissues or mucous membranes could be exposed and contaminated with the HCW's blood.
- An instrument or needle contaminated with the blood of the HCW is inadvertently introduced to the patients tissues.
- Bleeding from another site of the HCW such as nosebleed into a patients open tissues or mucous membranes.
- Patient bites HCW and is exposed to their blood.

When a reverse contamination injury occurs, the clinical procedure should be stopped as soon as reasonably practicable, and First Aid initiated. In this case the healthcare worker is classed as a Source Patient and will require to be assessed and consented for screening of BBV. The patient should be notified of the exposure and appropriately assessed and managed as the recipient.

<u>Healthcare worker/ Staff recipient</u>:
Arrange for a clotted blood sample (red topped blood bottle) to be taken requesting for '**serum store'.** This should be taken where possible on the same day of the incident and within 3 days of the exposure**.** This sample is required for storage and kept for a minimum of 2 years. This is not usually for routine testing and acts as a baseline should the sample be required to be tested in the future. Testing of this sample may be requested at a future date by Occupational Health with the healthcare worker's specific consent.

The blood form/ request for the recipient blood (healthcare worker) sample should clearly state the recipient's full details (name, DOB). In the clinical details section state, **'Inoculation Incident recipient' and the date of the incident**. In brackets add the source details (name and DOB). Bloods can be taken either at place of work (where able/ if clinical area), in the Occupational Health department or via Blood Clinic. Occupational Health will advise on this,

based on individual circumstances. If required to attend Blood Clinic, the sample collection should be classed as a priority and fitted in the clinic schedule as an urgent case

- Send both the blood samples/ forms to Microbiology (separately)
- If urgent testing of the source patient is required, such as defined within criteria of 'high risk', contact the Microbiology Department to arrange. Out of hours contact the On Call Microbiologist/ Pathology labs.
- The results of source patient blood tests and arrangements for follow-up blood tests on the recipient (the healthcare worker) will be coordinated by Occupational Health. Occupational Health are responsible for the follow up of the Source patient results solely for the purposes of ongoing management of the affected staff/ recipient.

6.5 Inoculation incidents affecting Trust staff in the Community.

Community staff should follow this policy as closely as possible, however, it is accepted that due to accessibility of staff, it may be the person who has sustained the inoculation incident who needs to also undertake the preliminary risk assessment. They should contact the senior clinician or Manager to then take consent and bloods from the source patient.

6.6 Documentation

- Complete an Incident Report / Datix detailing the incident, name of source patient (if known) and confirm that the actions (in 6.2 – 6.4) have been taken.
- Ensure that the incident and consent for tests has been documented in the Source Patient medical records.
- The inoculation incident assessment, subsequent management and any related records will be stored on confidential employee Occupational Health records.

7 Procedure for issuing Post Exposure Prophylaxis (PEP) for HIV

- The decision to prescribe PEP will be made after the inoculation incident risk assessment has been completed and OH contacted in working hours by the HCW (see Appendix 2).
- Where clinically indicated Occupational Health will liaise with GUM Specialists for assessment and initiation of PEP
- Out of hours, weekends and on Bank Holidays the decision to prescribe PEP will be made by the Emergency Department when clinically indicated (see Appendices 3-5)

PEP should be routinely offered to reduce risk of HIV transmission in the following scenarios:

Following an occupational exposure (sharps or mucosal splash) from an index case known to be HIV positive with an unknown or detectable HIV viral load

PEP is generally not recommended but considered in a scenario where there are clear specific extenuating factors increasing the risk of transmission:

Sharps and splash injuries where the index case is from a high-risk group, but the HIV status is unknown.
Human bite if the index case is HIV positive with an unknown or detectable viral load.

The British HIV Association (BHIVA) fully reviewed and updated their guidelines for post exposure prophylaxis (PEP) to HIV in 2021 (NICE accredited). This serves to provide evidence based guidance on the best clinical practice in the provision, monitoring and support of PEP for the prevention of HIV acquisition, which includes following an occupational exposure/ injury. The guidelines have been incorporated within this policy and cover when to prescribe PEP, what antiretroviral agents to use/ regimes and how to manage PEP. A Summary table of when PEP is indicated/ prescribing recommendations is provided (Appendix 3)

Guidelines for PEP and the following Inoculation Incident situations are available (Appendix 4):

- Sharps and mucosal splash injuries with an index case/ source patient of unknown HIV status
- When to prescribe PEP following human bites
- Sharps and mucosal splash injuries with an index case known to be HIV positive

Assessment for PEP is on an individual basis, risk and circumstance. Please see Appendix 5, for the Risk Assessment Proforma to be used by Clinicians in the Emergency Department (BHIVA 2021). This includes the assessment tool, provides a management plan and gives discussion points for the individual commencing PEP.

The first line recommended regimen for PEP has been updated to Tenofovir Disoproxil 245 mg/ Emtricitabine 200mg fixed dose combination plus Raltegravir 1200mg (600mg x2) **once daily** for 28 days. PEP should be initiated as soon as possible after exposure, preferably within 24 hours. It is not recommended to initiate PEP beyond 72 hours after exposure (UK Guidelines for the use of HIV Post-exposure prophylaxis, British HIVA Association 2021). **PEP packs are to be made available as a 28 day supply**, from GU Medicine (in OH working hours) and also from the ED department out of hours as per recommended guidance from NHS England. If commenced in ED, the health care worker must be advised to contact Occupational Health the next working day.

The earlier the initiation of PEP, the greater the efficacy of the treatment. Good adherence is required to the PEP regimen and completion of the 28-day course. See appendices (8-11) for the following:

- Pre printed prescription for PEP and information re Drug-Drug interactions and PEP regimes
- Patient information leaflet on PEP/ treatment for HIV
- Discussion points for the Clinician when commencing HIV-PEP

Risk assessment and counselling of the affected healthcare worker are important to determine whether PEP is indicated and to manage individual concerns. The decision to administer PEP should be based on the risk of HIV acquisition and not to manage a state of acute anxiety following a potential HIV exposure. Good communication, assessment and information is paramount to the affected/ injured individual. Occupational Health will provide initial and ongoing support to the health care worker following an inoculation incident and will liaise with and involve in the care management, the GU Specialist Team/ Virology/ Microbiology as required. Further counselling will be offered when indicated.

Prior to starting PEP, blood should be taken for the following tests;

- Creatinine (and eGFR)
- ALT (Alanine transaminase)
- Hep C antibody
- HIV screen
- If not known to be vaccinated and immune to Hepatitis B; Hep B antibody titre, Hep B surface antigen and Hep B core antibodies.

Routine renal and liver function test monitoring after initiation of PEP is not necessary unless clinically indicated or if baseline bloods are abnormal. The above blood samples will be taken in the GU clinic or in ED as appropriate to where the PEP is to be initiated,

A pregnancy test is advised for all women of childbearing age considering PEP.
Pregnancy is not a contraindication for PEP. Pregnant women are at increased risk of HIV transmission and the high viraemia associated with primary infection would lead to a high likelihood of intrauterine infection. A thorough risk assessment is essential prior to commencing PEP. The possible risk of this medication taken in pregnancy needs to be carefully balanced against the risk of contracting HIV infection following the exposure.

Alternative PEP regimes during pregnancy are recommended. Other drug combinations might also be required if the Source Patient is known to have a drug resistant HIV infection or if the affected health care worker is taking medications that interact with the first line regime (see Appendix 10)

Follow up for recipients/ health care workers requiring PEP:

The Occupational Health clinician will contact the GU Specialist Team to refer and arrange for the recipient to receive a follow up assessment if PEP has been commenced in ED (out of OH hours).

Individuals experiencing a skin rash or flu like illness while or after taking PEP should be advised to attend for urgent review and assessment at the GU Medicine clinic to exclude HIV seroconversion. Occupational Health should be updated of such events.

Occupational Health has the responsibility for follow up blood testing (BBV screen), for Occupational Injuries/ Exposures and will advise and arrange when required, with the health care worker accordingly. This includes for those staff that initiated/ completed PEP. Follow up testing will depend on available Source Patient results and the individual case, as guided by Occupational Health procedures.

In practice there may be individual circumstances where at the time of the incident/ exposure the HIV status of the Source Patient was unknown and following risk assessment, HIV-PEP was commenced. If the Source Patient later proves to be HIV negative on testing and there are no ongoing risks, Occupational Health will review in conjunction with support and advice from the GU Specialist Team for decisions on whether the PEP can be discontinued. As the PEP packs are due to be issued as a complete 28 days' supply as advised by NHS England, any unused medication will require to be returned to the Pharmacy Department UHDB

8 Procedure for issuing Post exposure prophylaxis for Hepatitis B

The decision whether hepatitis B prophylaxis should be considered will be made by Occupational

Health (8.30am – 4.00pm, Monday-Friday excluding bank holidays) in consultation with the Consultant Microbiologist based on individual circumstance. Out of hours this will be undertaken by the Emergency Department.

Chronic Hepatitis B remains the most prevalent of the blood borne viruses globally. Healthcare workers who have received Hepatitis B vaccinations are tested for immune response and generally develop good levels of immunity. However around 10% of individuals do not respond to the vaccine. Healthcare workers might be incompletely vaccinated at the time they sustain an Inoculation incident. For the unvaccinated or non-responder, the risk from a needlestick/ sharps injury to Hepatitis B infected blood can be 1 in 3. This is dependent on the viral load and Hepatitis B e antigen (HBeAg) status of the Source Patient/ individual.

Hepatitis B vaccines and Hepatitis B immunoglobulin (HBIG) are available to provide effective PEP when required. Decisions about the appropriate HBV-PEP must take in to account the affected workers Hepatitis B vaccination history in addition to the Source Patients status and infectivity. Guidance for appropriate post-exposure interventions are shown in Appendix 12 (Green Book, Chapter 18, 2022)

Hepatitis B immunoglobulin is required in such rare circumstances.

- The affected worker is known to be a non-responder to Hepatitis B vaccines and the Source Patient Hepatitis B status is positive (current infection) or considered high risk, unknown.

- The affected worker has at the time of the incident received either no or only one dose of Hepatitis B vaccines and the Source patient is known to be Hepatitis B positive (current infection)

In the event Hepatitis B immunoglobulin is required, its efficacy works best within 12 hours after the incident and ideally should be given within 48 hours. It is considered of little value after 7 days.

9. Hepatitis C

- Currently there is no available vaccination or post exposure prophylaxis for Hepatitis C. Therefore, HCV poses the greatest occupational Blood Borne Virus infection risk

- For inoculation incidents sustained from a known or high-risk Hepatitis C positive source, Occupational Health will provide follow up with appropriate blood tests, support and advice. Post exposure management is aimed to detect possible seroconversion early and so that specialist assessment and treatment can be sought if required.

10. Exposure to Unknown Source / Discarded Needle

Where it is not possible to identify the source individual (e.g. needlestick injury from a discarded needle), a risk assessment should still be completed by the nurse in charge to determine whether the exposure was a significant risk. The risk assessment will consider the circumstances of the exposure and the epidemiological likelihood this item is contaminated with HIV or another blood borne virus.

11. Working Role of the staff/ recipient following an Inoculation Incident:

Under normal circumstances, employees including those undertaking EPP (Exposure Prone Procedure) work can continue working, performing all duties after an inoculation incident. However, should the employee develop any symptoms suggestive of a BBV they must discuss with Occupational Health immediately. For such cases, or if follow up testing indicates that infection has been acquired, Occupational Health will review and advise on fitness for work. Information and support will be provided on any clinical follow up required or referral to a Specialist.

If follow up testing has been advised by Occupational Health;

Until follow up has been completed and BBV seroconversion has been ruled out, Healthcare Workers must comply and have strict adherence to the Trust Infection Control policies, practice principles of safer sex and avoid the donation of blood or other bodily fluids/ tissue.

12. Training

- Infection Prevention & Control training (including Inoculation Incident procedure) is a compulsory requirement for all staff and is part of the Trust's Induction Program.
- Each member of staff identified in the Training Needs Analysis will have an update every 2 years.

13. Monitoring Compliance and Quality Effectiveness

Monitoring Requirement:	To monitor the incidence, type of inoculation incidents and emergent risks/themes providing feedback to clinical staff via the Trust Sharps Safety Management Group/ Health & Safety. Relevant issues to be escalated to the Trust Board.
Monitoring Method:	The Infection & Prevention Control Team will undertake routine Infection Control Audits, including identification of safe sharps practice annually and as required. These findings are reported in the first instance to the Senior Matron who will produce an Action Plan in order to rectify any areas of concern. Inoculation Incident statistics from Occupational Health data Datix reports
Report Prepared by:	Occupational Health Services will collate the Inoculation Incident Statistics
Monitoring Report presented to:	A summary of Divisions Audit results will be reviewed by the Infection Control Committee Occupational Health will provide reports to the Trust Safety Management Group/ Health & Safety detailing compliance with the policy. Relevant issues will be escalated in the Infection Control report to Quality Assurance Committee/Risk Management
Frequency of Report	Annual Summary of Audit Results

14 References

- *Control of substances hazardous to health (Fifth edition). The Control of Substances Hazardous to Health Regulations 2002 (as amended). Approved Code of Practice and guidance* L5 (Fifth edition) HSE Books 2005 ISBN 978 0 7176 2981_7
- *Management of health and safety at work. Management of Health and Safety at Work Regulations 1999. Approved Code of Practice and guidance* L21 (Second edition) HSE Books 2000 ISBN 978 0 7176 24881
- *Health and Safety at Work etc. Act 1974* (c.37) The Stationery Office 1974 ISBN 978 0 10 543774 1
- *The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995: Guidance for employers in the healthcare sector* Health Services Information Sheet HSIS1 HSE Books 1998 www.hse.gov.uk/healthservices/information.htm
- Department of Health. (2008), HIV post – exposure prophylaxis: Guidance from The UK Chief

Medical Officers' Expert Advisory Group on AIDS

- UK National Guidelines for HIV Testing 2008 (Sept 2008) British HIV Association British Association of Sexual Health and HIV British Infection Society

- The Health and Social Care Act (2008): Updated 2015. Code of Practice on the prevention and control of infections and related guidance

- Department of Health and UKHSA (published 2013). Immunisation against Infectious Diseases: The Green Book. Updated version 2021. Individual chapters updated regularly www.gov.uk.

- Infection Control Nurse Association (2003) Reducing sharps injury, prevention and risk management Bathgate: ICNA

- UK Health Departments (1998) Guidance for Clinical Healthcare Workers: protection against infection with blood borne viruses. Recommendations of the Expert Advisory Group on AIDS and the Advisory Group on Hepatitis

- NHSLA Risk Management Standards 2012-13 for NHS Trusts providing Acute, Community, or Mental Health & Learning Disability Services and Non-NHS Providers of NHS Care Directive 2010/32/EU - Prevention from Sharp Injuries in the Hospital and Healthcare Sector

- British HIV Association (BHIVA) 2021: UK Guideline For The Use Of HIV Post-Exposure Prophylaxis. Post consultation version

- HSE (2013) Health and Safety Sharps Instruments In Healthcare Regulations. Guidance for employers and employees information sheet. No.7

- Blood & Bodily Fluid Exposures in 2020. Results From A Survey Of RCN Members (May 2021) www.rcn.org.uk/publications. Publication code 009687

APPENDIX 1

Inoculation Incident Advice

An INOCULATION INCIDENT is:

- Contaminated needle stick / sharps injury
- Splash of blood or body fluid to the eye / mouth or non-intact skin.
- Splash of blood or body fluid to an open wound
- Human bite that breaks the skin
- Scratch that breaks the skin and another person's blood or body fluid is involved

- Wash the affected area under running water and encourage free bleeding. Do not scrub affected site
- Dry and apply a waterproof dressing.
- Irrigate the eye or mouth well with water or an eye wash solution.
- Notify the person in charge immediately

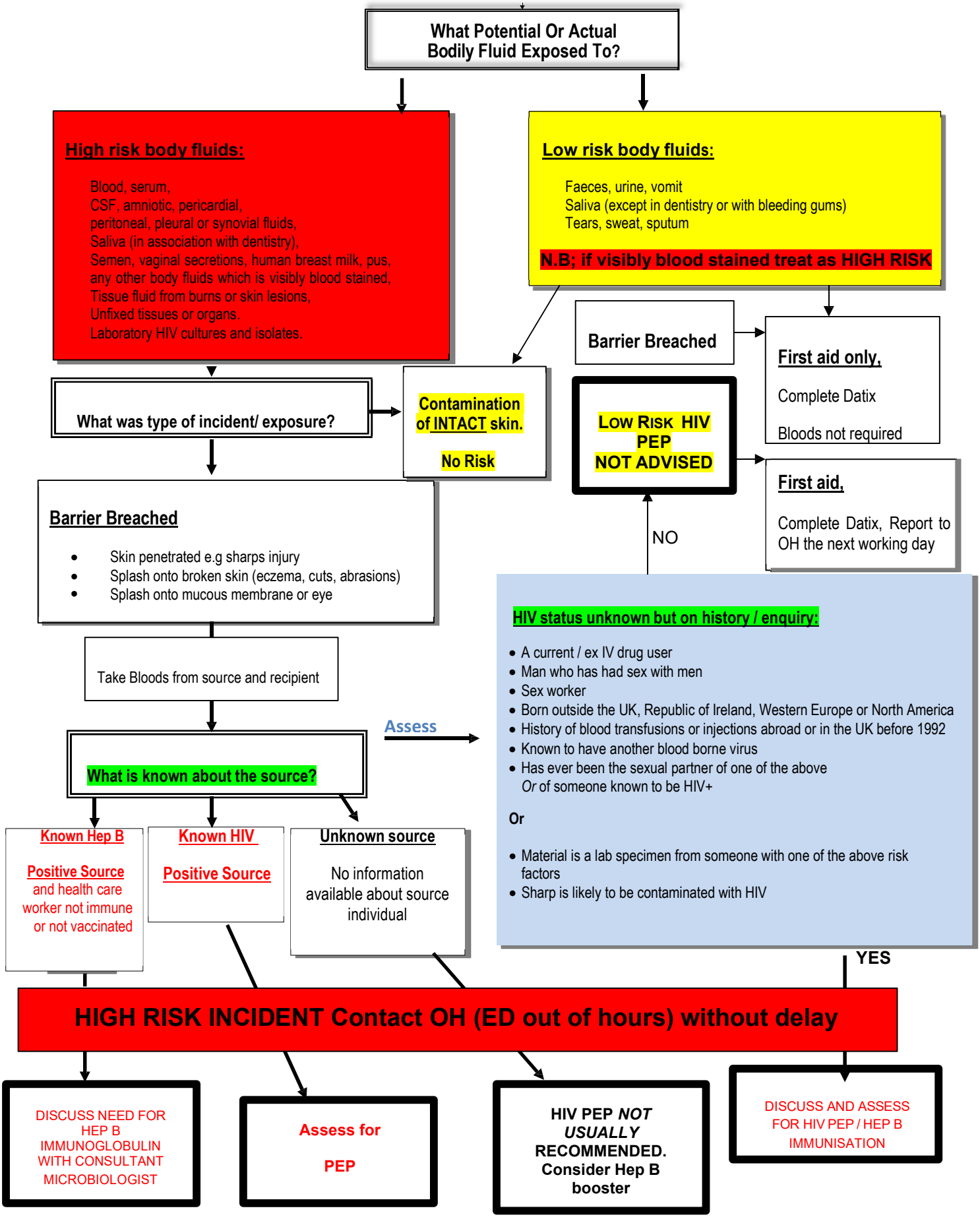
ACTIONS:

- The person in charge/ responsible Clinical Team must carry out a **preliminary risk assessment** (Appendix 2 of Inoculation Policy)
- Incidents involving unknown or high-risk source patients/ individuals (e.g. possible HIV or Hepatitis B/C exposure, contact **without delay** Occupational Health (Monday – Friday, 8.30am-4.00pm excluding Bank Holidays. At all other times: contact the Emergency Department and ensure if requested, the health care worker attends immediately. Inform Occupational Health the next working day
- All other Inoculation Incidents involving high risk fluids should be reported to Occupational Health as soon as possible. If out of hours, at weekends and on Bank Holidays leave a message on the answer machine/ email Occupational Health and contact the Emergency Department for advice or concerns
- Person in charge to arrange blood collection from the source patient and the healthcare worker in a red topped blood bottle. Obtain patient/ Source consent and request for HIV, Hepatitis B and Hepatitis C testing as per policy. Clearly document on the request form clinical details 'Source patient of inoculation incident'. The lab request form for the healthcare workers' sample should be marked clearly 'Serum Stored only, not for testing' and 'staff recipient of inoculation incident' in the clinical details. **Do not** send samples to the labs together in the same bag
- Datix to be completed

APPENDIX 2

ASSESSMENT OF THE RISK FROM AN INOCULATION INJURY

The flow chart below indicates when PEP may be indicated. The senior member of staff can seek advice on the assessment of the risk of an inoculation injury from the Occupational Health (OH) Department (or the Emergency Department (ED) when the Occupational Health Department is not open).



Appendix 3: Summary Table Of PEP Prescribing Recommendations

	Index HIV positive		Index of unknown HIV status	
	HIV VL unknown or detectable	HIV VL undetectable	From high prevalence country / risk-group (e.g. MSM) [a]	From low prevalence country / group
OCCUPATIONAL AND OTHER EXPOSURES				
Sharing of injecting equipment	Recommended	Not recommended [b]	Generally not recommended[e]	Not recommended
Sharps injury	Recommended	Not recommended [b]	Generally not recommended [c,e,f]	Not recommended
Mucosal splash injury	Recommended	Not recommended [b]	Generally not recommended[c]	Not recommended
Human bite	Generally not recommended [g]	Not recommended	Not recommended	Not recommended
Needlestick from a discarded needle in the community			Not recommended	Not recommended

Recommended: the benefits of PEP are likely to outweigh the risks, PEP should be given unless there is a clear reason not to.
Consider: the risk of HIV transmission is low, the risk / benefit balance of PEP is less clear. The risk should be assessed on a case by case basis taking into consideration factors shown in footnotes c and d below.
Generally not recommended: the risk of HIV transmission is very low, the potential toxicity and inconvenience of PEP is likely to outweigh the benefit unless there is a clear specific extenuating factor which increases the risk (see footnotes c, below). We anticipate PEP should very rarely be given when the risk has been assessed and discussed (section 6.1.2 and 6.2.1.2)
Not recommended: the risk of HIV transmission is negligible and PEP should not be given

[a] High prevalence countries or risk-groups are those where there is a significant likelihood of the index case individual being HIV-positive. Within the UK at present, this is likely to be MSM (men who have sex with men), people who inject drugs from high-risk countries (see d below) and individuals who have immigrated to the UK from areas of high HIV prevalence, particularly sub-Saharan Africa (high prevalence is >1%). HIV prevalence country specific HIV prevalence can be found at https://aidsinfo.unaids.org

[b] The index case has been on ART for at least 6 months with an undetectable plasma HIV viral load at the time of last measurement and within the last 6 months) with good reported adherence. Where there is any uncertainty about HIV VL results or adherence to ART then PEP should be given. The viral load threshold considered 'undetectable' in the PARTNER 1 and 2 and HPTN052 studies was <200 copies/ml.

[c] Factors that influence decision-making in all exposures: More detailed knowledge of local HIV prevalence within index case sub-population [a]. The recommendations relate to high-risk groups living in the UK (based on the known prevalence of detectable HIV viraemia in the UK, guideline table 1). Where the index case is from a high risk group and normally resides outside the UK, the risk may be greater and where there is doubt PEP should be given.

[e] HIV prevalence amongst IDUs varies considerably depending on whether there is a local outbreak and country of origin and is particularly high in IDUs from Eastern Europe and central Asia. Region-specific estimates can be found in the UNAIDS Gap Reporthttp://www.unaids.org/sites/default/files/media_asset/05_Peoplewhoinjectdrugs.pdf.

[f] Factors that may influence decision-making include in occupational exposures: Deep trauma or bolus of blood injected

[g] PEP should only be considered after a bite if all three criteria are met: a) the biter's saliva was visibly contaminated with blood; b) thebiter is known or suspected to have a plasma HIV viral load >3.0 log copies/ml; and c) the bite has resulted in severe and/or deep tissue injuries

BHIVA 2021, UK Guidelines for HIV PEP, p34.

Appendix 4: When to prescribe PEP following Occupational exposures

HIV positive Source Patient

PEP is recommended following a high-risk injury (sharps or mucosal splash) if the index case/ Source Patient is known to be HIV-positive and is not on ART/ treatment for >6 months with a suppressed viral load within the last 6 months.
PEP is generally not indicated following a sharps injury if the index case has been on ART for at least 6 months with an undetectable HIV viral load (at the time of last measurement and within the previous 6 months) and reported good adherence. However due to lack ofdirect evidence, a case by case decision can be made depending on the nature of the injury.
PEP is not recommended following a splash injury If the index case is known to have a sustained undetectable viral load
PEP is not recommended where there is no or negligible risk of HIV transmission e.g. through intact skin that comes into contact with HIV infected blood or other bodily fluids.

Source Patient of **unknown** HIV status

PEP is not recommended following a sharps or mucosal splash injury if the index case (Source Patient) is untested but from a low risk group. See Summary Table, PEP recommendations
PEP is generally not recommended following a sharp or mucosal splash injury if the index case is untested and from a high-risk group (e.g. MSM or PWID/ people who inject drugs), unless there were other factors that increased likelihood of transmission (e.g. a deep injury or blood bolus injected or a sharps injury from a PWID in the context of a local outbreak)
All efforts should be made to seek prompt voluntary HIV testing of the index case
Index case HIV testing should not delay PEP initiation where indicated
If the index case/ Source Patient is unable to give informed consent for HIV testing (e.g. unconscious, altered mental status) then HIV testing can be performed if it is in the patient best medical interests, (part of their investigations and care)

If the index case is unknown or thought to be of non-UK origin further information can be found using this link https://aidsinfo.unaids.org.

BITES:

In general PEP is not recommended following a bite as, although the precise risk of transmission is unknown, it is likely to be negligible
However, PEP could be considered for patients who fulfil ALL of the three following criteria: a) the biter's saliva was visibly contaminated with blood; b) the biter is known or suspected to have a plasma HIV viral load >3.0 log copies/ml; and c) the bite has resulted in severe and/or deep tissue injuries

APPENDIX 5:

Post Exposure Prophylaxis Risk Assessment Proforma for Use in Emergency Departments

This checklist is an aid to clinical practice only and does not replace local expert advice where indicated. For further information, please refer to the British Association of Sexual Health and HIV PEP 2021 guideline

Section 1:	
Date:…….Time:…… …….. Seen by (Name / Designation):	Patient Name: DOB: Address:

Date of Potential/Actual Exposure ..../……/…… Time of exposure …….

Number of hours between exposure and consultation …….

Note: must be less than 72 hours since exposure to be eligible for PEP

Past Medical History & Current Health Status:
……
……
……
……

Medication History: (including over the counter / herbal remedies / multivitamins / recreational drugs)
……
……
……

Allergies: ……

Contraception:……

Is the patient pregnant or at risk of pregnancy?.....

First day of Last Menstrual Period / cycle length (consider emergency contraception)

……..

Type of exposure (tick one)

☐ Occupational injury / Other Exposure, including injecting drug use

☐ Sexual Exposure

Section 2: Occupational injury / Other Exposure

Brief description of exposure**:**

……

……

……

……

……

……

☐ **Sharp instrument/needlestick**: ☐ hollow needle ☐ solid needle ☐ BM stick lancet ☐ Other:……

Were gloves worn? ☐ Yes ☐ No Did needle pass through glove ☐ Yes ☐ No ☐ Not known

☐ **Splash injury**: ☐ to eye/mouth ☐ Splash to broken skin ☐ Splash to intact skin

☐ **Bite/Scratch** ☐ Other (specify)…… Depth of injury: ……

Material exposed to: ☐ Blood / Plasma ☐ CSF ☐ Saliva ☐ Other (specify)……

Was wound made to bleed immediately? ☐ Yes ☐ No ☐ Not known

Was injury washed? ☐ Yes ☐ No ☐ Not known

If unknown HIV status, has index case / patient been consented and tested for BBV (HIV, Hep B/C)?

☐ Yes ☐ No ☐ Not known

Details:……
……

Section 3: Details of Source Patient

Name/ Description:……

DOB/Age:……

Address/Area:……

Tel number:……

Known Hepatitis B positive: ☐ Yes ☐ No ☐ Not known

Known Hepatitis C positive: ☐ Yes ☐ No ☐ Not known

HIV status

☐ Definitely known HIV + (Status known to patient or HIV clinic)
☐ Probable HIV + (Patient told by contact or by someone else)
☐ Unknown HIV status

Is patient on antiretroviral treatment? ☐ Yes ☐ No ☐ Not known / unsure
Does the patient have an undetectable viral load? ☐ Yes ☐ No ☐ Not known / unsure
Patient HIV clinic location if known:……...

Section 4: Summary table on PEP eligibility

	Source HIV status			
	HIV positive		Unknown HIV status	
	HIV VL unknown / detectable	HIV VL undetectable	From high prevalence country / risk-group (e.g. MSM) [a]	From low prevalence country / group
OCCUPATIONAL AND OTHER EXPOSURES				
Sharing of injecting equipment	Recommended	Not recommended	Generally not recommended [e]	Not recommended
Sharps injury	Recommended	Not recommended	Generally not recommended [c,f]	Not recommended
Mucosal splash injury	Recommended	Not recommended	Generally not recommended [c]	Not recommended
Human bite	Generally not recommended [g]	Not recommended	Not recommended	Not recommended
Needlestick from a discarded needle in the community			Not recommended	Not recommended
Details of footnotes can be found in the full BASHH 2021 PEP guideline document online. https://www.bashh.org/guidelines				

Section 5: Patient eligible for PEP? (decision to be based on table in appendix below)

☐ Yes, recommended ☐ Not Recommended ☐ Consider

Recommend provision of the full 28 day PEP course of where possible

PEP starter pack prescribed ☐)

(See full guideline or seek URGENT specialist advice if any uncertainty or alternative regime required)

Emergency contraception given ☐ Yes ☐ No Details……..

Discussion points with the patient (Please tick)

- The need for baseline bloods (including HIV test) ☐
  N.B Sample for serum store only if PEP not indicated. Hep B antibody titre if immunity unknown
- Antiretrovirals are unlicensed for PEP ☐
- Lack of conclusive data for PEP efficacy ☐
- Importance of adherence to optimise efficacy ☐
- Start PEP as soon as possible to maximise efficacy ☐
- Advised too late if commenced after 72 hours ☐
- Length of PEP is 28 days ☐
- Drug side effects discussed ☐
- Drug interactions including multivitamins, iron, antacids (advised to avoid whilst on PEP) ☐
  Drug interactions including over the counter drugs such as multivitamins/antacids/iron (iron should not be used with once daily raltegravir or if an essential medication, iron should be spaced at least 4 hours apart from twice daily raltegravir dosing)

- Seek urgent attention if symptoms of seroconversion (flu-like symptoms / rash) ☐
- Advise condoms until final HIV test (in 10.5 weeks or after) ☐
- Emergency contraception given (if applicable) ☐
- Hepatitis B vaccine/ immunoglobulin advised or indicated (if unsure if immune or in cases of sexual assault) ☐

- Given PEP leaflet ☐
- If given a starter pack (rather than the full 28 day course),advised of the need for urgent follow-up before the starter pack runs out to receive the rest of the course ☐
- For occupational exposures: advised urgent follow up with occupational health ASAP and no later than within 72 hours ☐

Baseline tests to be obtained by Accident and Emergency clinician

Tests	Taken		Taken		Taken		Taken
HIV		Hep B core antibody*		Hepatitis C antibody		LFT (ALT)	
Hepatitis B surface Antigen*		Hepatitis B surface antibody*		Creatinine and eGFR		Pregnancy test (if applicable)	

*If the attendee has completed the hepatitis B vaccination course and has documentation of HepBsAb ≥10 IU at any time they are deemed a vaccine responder. If they are immunocompetent (e.g. HIV-negative) they do not require any further hepatitis B testing or follow up

APPENDIX 6:

Source Patient Information Leaflet:

Sometimes healthcare workers can be injured whilst caring for a patient. For example, by a needle/other medical device or via a splash of bodily fluids in to eyes, mouth or non-intact skin

When this happens, the potential transfer of blood or body fluids can leave the healthcare worker exposed to infection or illness.

This information sheet explains what course of action the hospital needs to follow when these or similar incidents happen. The procedures are following Department of Health guidelines.

If you are worried or have any concerns about any of these points, please ask to speak to a member of your care team, the hospitals Infection Control Team or the hospitals Assistance and Complaints Service.

Why is the injury relevant to me?

- A healthcare worker who was carrying out tests, procedures or care for you, was injured by equipment that was contaminated or had been exposure to your blood or bloodstained body fluids.

THIS IS NOT YOUR FAULT

- You were possibly not even aware the injury had occurred.
- This will in no way have any effect on your current care.
- As the "source patient" (the patient cared for when the injury happened) we need to ask you to consent to having a blood test. This is because the healthcare worker could be at risk from infection or illness – through the transfer of blood or body fluids.

What will the tests be for?

A member of the team caring for you will ask for your permission and written consent to take a blood test to test for three viruses found in blood:

- Hepatitis B
- Hepatitis C
- Human Immunodeficiency Virus (HIV)

A member of the team caring for you will also ask you some questions (these are similar to those asked prior to Blood donation)

These questions will provide us with information about any possible risk factors associated with contracting the above blood-borne viruses.

They will include questions about your lifestyle, where you have lived and if you have needed healthcare in other countries.

What does the test involve?

The test is a blood test, possible similar to ones you may have undergone previously. This blood test will only test for the viruses as detailed above which you will have consented for. No other tests will be carried out on this blood sample.

Would all patients have a test like this?

If a patient is the known "source" of an injury or exposure incident they will be asked to have this blood test. It is a standard procedure recommended by the Department of Health and it helps to reduce the risks to our staff. You are not being singled out or judged.

Some of the other questions we will need to ask:

How might I have acquired any of these viruses?
Some people have them at birth, acquired from their mother. Otherwise, they can be transmitted during sex from an infected partner, or when drug users share needles, or perhaps even from a dirty needle when someone is having a tattoo or body piercing done.

What are the consequences of being tested?
For most people the advantages outweigh the disadvantages, but it has to be your choice. If the tests are all negative, then that's reassuring, and there are no drawbacks of having been tested.

If one is positive, then this may come as a shock, but the specialist care is likely to be of benefit to you. You will then have the opportunity to be able to start treatment to improve your own health and be in a position where you can take action to prevent yourself from infecting others close to you with what may be a life threatening illness.

Do I need to decide whether to have the test straight away?
The sooner we know the result of your test, the sooner we can plan treatment, if necessary, both for yourself and for the healthcare worker who has been exposed to your blood or body fluids. In the interim, the healthcare worker may be advised to start on a strong course of medication as a preventative measure – receiving negative results quickly will allow this treatment to be stopped. We will try to answer any questions you might have in connection with the test.

How can we let you know the results of the tests?

Do you consent to us informing the injured healthcare worker of your test results?

Do you wish for the results to be placed on your medical file?

Do you wish for us to send the results to your GP?

Can I refuse to have these tests?
Yes, this will not have any effect on the current care and treatments you are receiving.

What happens if any of the test results are positive?
When you are informed of the results you will be advised about the next steps.

This could entail a further blood test to confirm the results, or you may need to be referred to a specialist team for further investigations or treatments.

If you want to discuss or ask any questions, before you undergo the blood test, please ask a member of your care team.

Useful sources of further information and advice

The Department of Genitourinary Medicine, Florence Nightingale Community Hospital, Derby
0800 3283383

The Terence Higgins Trust (a registered charity) 0115 8820121 www.tht.org.uk

NHS 111 (free-to-call single non-emergency number medical helpline run by NHS)

APPENDIX 7

Seeking consent to test a source patient for blood borne viruses following an inoculation incident; the mental capacity of the source patient to consent

The individual who obtains consent from the source patient should be satisfied that the person has given explicit informed consent to either testing of their stored blood or the taking of a blood sample for this purpose.

Consent from the source patient should be obtained from a healthcare worker, however this should not be from the worker who sustained the injury.

Consent for blood borne virus testing should take into consideration the following factors;

- The individual's ability to make informed choices
- The individual's competency to consent
- Consent must be voluntary
- The individual should understand the purpose of testing
- The individual should be made aware how and when they will be informed of the test results

The tests which have been agreed to and who had the conversation with the source patient should be clearly stated in their medical records.

Consent for blood borne virus testing in circumstances where the source patient may lack the capacity to consent.

1. The Human Tissue Act (2004) which governs the obtaining of source patient consent following an Inoculation Incident involving a healthcare worker supersedes previous General Medical Council (GMC) guidance in this area. The source patient's consent to testing must always be gained. Where the source patient lacks the capacity to consent, HIV testing may **not** be undertaken for the sole benefit of the injured healthcare worker following an inoculation incident. If the patient does not wish to know the result, the option of testing without any documentation should be considered.

Legislation in England, Wales and Scotland provides a framework for decision-making on behalf of adults aged 16 and over who lack capacity to make decisions on their own behalf. The Mental Capacity Act 2005 applies to England and Wales.

2. A person lacks capacity if, at the time the decision needs to be made, he or she is unable to make a decision because of a mental disorder, or is unable to communicate their decision. Key points to consider when assessing capacity:

- The assessment of capacity relates to the specific issue in question, in this case consent to HIV testing
- Start from the presumption that the patient has capacity to make this decision
- Consider whether the patient understands what decision they are being asked to make and can weigh up the information relevant to the decision; do they understand the consequences of making a choice?
- Take all possible steps to help patients make a decision for themselves (e.g. provide information in a more accessible form – drawings, tapes etc.). If you judge that a patient lacks capacity to consent to a HIV test you should consider whether this is temporary or permanent. If temporary, you should defer testing until the patient regains capacity, unless testing is immediately necessary to save the source patient's life or to prevent a serious deterioration of their condition.
- If the lack of capacity is, or is likely to be, permanent you should seek a decision from any person with relevant powers of attorney or follow the requirements of any valid advance statements. If the patient has not appointed an attorney nor left a valid advance statement, HIV testing may be undertaken where

this is in the best interests of the source patient (England and Wales) or is necessary and of benefit to the source patient.

- For a deceased source patient, the Consultant in charge of the patient may seek consent from the source patient's relatives. The Coroner has additional powers to request HIV testing

Testing infants, children and young people

In England and Wales children are defined as those under 18 years old (Children Act 1989). Under English law young people aged 16 years or over are assumed to have the capacity to consent to medical treatment and should be treated in the same way as adults. Young people under 16 years without a parent or guardian should be assessed for competency to consent. If a child lacks the capacity to consent, then the consent of one parent or carer with parental responsibility is sufficient.

APPENDIX 8

HIV Post-Exposure Prophylaxis

Please read this information together with the Patient Information Leaflets enclosed with your medication.

These medicines are used in patients diagnosed with HIV infection, including pregnant women. This is what they are licensed for. However, for you, they are being used outside this license. You are taking them to prevent possible infection with HIV after a high risk exposure to HIV.

To be most effective these medicines need to be started within one hour of the high risk exposure although they can be started up to 72 hours after the exposure. The full course is 28 days in total and the PEP packs provided are due to be issued with the entire treatment regimen. The GUM Physician will co-ordinate you receiving further supplies of medication should you have been provided with a starter pack of 3 days supply.

Before you take your medicines you must inform the prescribing clinician if you have had a reaction to any of the ingredients in the past, are pregnant, breast feeding or suffer with liver or kidney disease. If you are on any other medications, prescribed or non-prescribed let your prescriber know. An alternative medicine may be given if you are known to have kidney failure or other health conditions.

Side effects: The medication can cause a number of side-effects including nausea (feeling sick), diarrhoea, headache and tiredness. These side-effects usually settle if you keep taking the medicines as directed. Serious side effects are rare. It is recommended you take the medication just after food.

Secondary Prevention:
It is important during the 12 week follow-up period that:

-You do not have unprotected sex (use condoms)
-You avoid donating blood, plasma, organs, tissue, or semen
-You avoid pregnancy and breastfeeding

This applies until you have been cleared of the risk of contracting a blood borne virus following this exposure. Occupational Health will arrange the necessary follow-up blood tests. These medicines also reduce the effectiveness of hormonal contraception, and this should not be relied upon while you are taking the medication.

Use in Pregnancy:
Tell your prescriber if you could be pregnant. The possible risk of this medication taken in pregnancy needs to be carefully balanced against the risk of you contracting HIV infection following this exposure. You may wish to speak to the Genitourinary Medicine doctor on call for further advice on taking this medication in pregnancy. This doctor has experience of prescribing this medication in pregnancy (an appointment will be arranged).
You are advised to avoid becoming pregnant or to father a child while taking these medicines. Loperamide, which is used to treat some of the adverse effects which may arise, is not recommended for use in pregnancy. Your doctor can discuss suitable alternatives if necessary.

Store the drugs in the containers provided at room temperature. Keep medicines out of reach of children.

If you have any further questions about these medicines, contact Pharmacy or the Occupational Health Department. Your confidentiality will be guaranteed.

APPENDIX 9

Pre-Printed Prescription to be used for HIV Post Exposure Prophylaxis
First Line Regimen:

Name:	
Date of Birth	
Hospital number (if available)	
Consultant (or other doctor) authorising HIV PEP prescription **Prescriber's signature, (and also prescriber's name written clearly in block capitals)**	
Bleep number and contact details of prescriber	
Date:	

Medication prescribed: HIV-PEP packs come as a 28 day supply

Note: *Truvada and Raltegravir are supplied within the PEP pack*
Cyclizine and loperamide are supplied separately.
*(**The prescriber should cross these out if they are not required.)***

Truvada (245 mg Tenofovir + 200mg Emtricitabine)
Take one tablet daily after food

and

Raltegravir 600mg film coated tablets
Take two tablets (1200mg) once per day after food

Cyclizine 50mg tablets
One tablet to be taken three times a day if necessary, for nausea or vomiting

Loperamide 2mg capsules x 30
Take two as an initial dose if needed for diarrhoea, then one after each loose stool if needed. Maximum 8 in 24 hours

Note. *The manufacturers of Loperamide recommend that it is avoided in pregnancy*

APPENDIX 10:

POTENTIAL FOR DRUG–DRUG INTERACTIONS

When prescribing HIV- PEP it is essential to ensure that the potential for drug–drug interactions is considered, therefore an accurate patient medication history should be obtained. Clinicians are advised to liaise with a HIV Specialist Pharmacist as required and/or use Liverpool Drug Interaction website (http://www.hiv-druginteractions.org)for this purpose. An assessment of medicines including the use of over-the-counter, supermarket and recreational drugs must be undertaken. Drug interactions: including over the counter drugs such as multivitamins/antacids/iron (iron should not be used with once daily Raltegravir or if an essential medication, iron should be spaced at least 4 hours apart from twice daily Raltegravir dosing)

HIV-PEP Regimes:

Recommended use of Tenofovir Disoproxil 245mg/Emtricitabine 200mg and Raltegravir 1200mg once daily as the regimen of choice for PEP
If there is evidence that the index case/ Source Patient has a current or past history of ART/ treatment failure, expert advice should be sought as to whether the PEP regimen should be modified in relation to ART history and/or resistance testing.
For women who are pregnant, Raltegravir 400mg twice daily is preferred (with Tenofovir Disoproxil 245mg/Emtricitabine 200mg). Where accessing Raltegravir 400mg might cause delay recommend using Raltegravir 600mg twice daily and switching at the earliest opportunity. Discuss with Pharmacist

APPENDIX 11:

Items to discuss with individual commencing PEP:

1. The rationale for PEP and risk of seroconversion
2. The lack of conclusive data for the efficacy of PEP
3. Start PEP as soon as possible and importance of adherence to optimise efficacy.
4. The potential side-effects of PEP
5. Drug interactions including over the counter drugs such as multivitamins/antacids/iron (iron should not be used with once daily raltegravir or if an essential medication, iron should be spaced at least 4 hours apart fromtwice daily raltegravir dosing)
6. Emergency contraception (if appropriate)
7. Seek urgent medical attention if they develop symptoms of possible seroconversion
8. The arrangement for early follow-up with either an occupational health or HIV/GU medicine clinic
9. Verbal consent and HIV test
10. The need to continue PEP for a minimum of 28 days if the baseline result is negative
11. The need to have a follow-up HIV test a minimum of 45 days after completion of the PEP course – this is a minimum of 10.5 weeks post-exposure if the 28 days course is completed
12. The need to use condoms until the follow-up HIV testing is negative
13. Coping strategies, assessment of vulnerabilities and social support

APPENDIX 12:

Table 18.7 Hepatitis B prophylaxis for reported exposure incidents: Green Book (Chapter 18, 2022)

	Significant exposure			Non-significant exposure	
HBV status of person prior to exposure	**HBsAg positive source**	**Unknown source**	**HBsAg negative source**	**Continued risk**	**No further risk**
Unvaccinated	Accelerated course of Hep B vaccine plus HBIG with first dose	Accelerated course of Hep B vaccine	Consider course of Hep B vaccine	Initiate course of Hep B vaccine	No HBV prophylaxis. Reassure
Partially vaccinated	One dose of HepB vaccine and finish course	One dose of HepB vaccine and finish course	Complete course of Hep B vaccine	Complete course of Hep B vaccine	Complete course of Hep B vaccine
Fully vaccinated with primary course	Booster dose of Hep B vaccine if last dose $\geq$ 1year ago	Consider booster dose of Hep B vaccine if last dose $\geq$ 1year ago	No HBV prophylaxis. Reassure	No HBV prophylaxis. Reassure	No HBV prophylaxis. Reassure
Known non-responder to Hep B vaccine (anti-HBs < 10mIU/ml 1-2 months post-immunisation)	HBIG Booster dose of Hep B vaccine. A second dose of HBIG should be given at one month	HBIG Consider booster dose of Hep B vaccine. A second dose of HBIG should be given at one month	No HBIG Consider booster dose of Hep B vaccine	No HBIG Consider booster dose of Hep B vaccine	No HBV prophylaxis Reassure