Guidelines for the Emergency Management of Injuries and Post-Exposure Prophylaxis (PEP)

(including needlestick and sharps injuries, sexual exposure and human bites) where there is a risk of transmission of bloodborne viruses and other infectious diseases



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BACKGROUND TO THE GUIDELINES

Introduction

Injuries where there is a risk of transmission of infection frequently present in emergency departments, sexual assault units, occupational health departments and primary care settings. Bloodborne virus (BBV) infections such as hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) are of particular concern because of the potential long-term health effects for people who become infected, the anxiety experienced by the injured persons, and the increase in their prevalence in the population in recent decades. The appropriate management of such injuries, in the emergency and follow-up periods, has important implications in terms of minimising the risk of transmission of BBVs and in allaying the psychological impact on the injured person.

Many emergency departments and occupational health departments throughout Ireland have developed guidelines for the management of injuries where there is a risk of BBV transmission. However, these guidelines differ in their scope (e.g. all BBVs versus HIV; all exposures versus occupational or sexual), their level of detail, and recommended actions, such as testing schedules and the use of post-exposure prophylaxis (PEP). The development of these guidelines was prompted by the idea of having standardised guidelines on the management of these injuries that could be used in all relevant settings throughout the country and that would be based on best available evidence and expert opinion.

Purpose and scope

The purpose of these guidelines is to provide comprehensive guidance on the appropriate management of injuries where there is a risk of transmission of BBVs and other infections. The guidelines are intended for use as follows:

Setting: Any medical setting where the patient first presents with the injury, for example, a hospital emergency department or occupational health department, a general practice, a dental practice, a Garda occupational health department, a clinic for sexually transmitted infections or a sexual assault treatment unit (SATU).

Patient population: Members of the public in a healthcare or community setting; healthcare workers (HCW) or other workers (e.g. members of the Garda or defence forces) in an occupational setting; adults and children; both recipients and sources of injuries.

Type of injury: Needlestick or other sharps injury, sexual exposure, human bites, exposure of broken skin or of mucous membranes. These guidelines do not cover injuries where the source is an animal.

Time: Emergency management on first presentation, and also arrangements for any necessary follow-up.

Content

The guidelines cover the following aspects of management: first aid, risk assessment, testing, treatment (including PEP for HBV and HIV), counselling and follow-up, records and documentation. Although the focus is mainly on BBVs, the management of other risks is also covered in brief.



The main questions covered by the guidelines are:

- What first aid treatment should be administered?
- Is the exposure significant?
 - What materials are significant for BBVs?
 - What injuries are significant for BBVs?
- How to assess the risk of transmission of BBVs?
 - What is the level of risk of HBV, HCV or HIV?
 - What factors in the injury increase the risk of transmission?
- How should the source be investigated?
- How should the recipient be investigated?
- What blood tests should be done and when?
- Who should receive HBV vaccine and/or hepatitis B specific immunoglobulin (HBIG)?
- When is HIV PEP indicated and what treatment protocol should be used?
- How should HCV exposure be managed?
- What reassurance can be given to the recipient?
- What precautions are advised?
- What follow-up is needed?

The content is arranged as follows:

- 1. Main body of text a summary protocol for case management from presentation to discharge.
- Appendices stand-alone flow charts and tables; data collection forms; template letters and information leaflets; detailed discussion and evidence base for specific aspects of assessment or treatment.

Methods

Working group

The working group that developed the guidelines is a sub-committee of the Scientific Advisory Committee (SAC) of the Health Protection Surveillance Centre (HPSC), and included professionals with the relevant expertise and experience, and target users of the guidelines. The disciplines represented were dentistry, emergency medicine, infection prevention and control nursing, infectious diseases, medical microbiology, occupational medicine (hospital and Garda), and public health medicine. The members were chosen to represent a professional body or because of their individual expertise. The Irish College of General Practitioners (ICGP) was unable to provide a representative but agreed to be available for consultation during the course of the guidelines development. The members of the working group and the organisations they represented are listed on page 10.

Search protocol

In developing the recommendations in these guidelines various sources of guidance were reviewed. Initially, existing guidelines for the management of needlestick injuries, bites, and other blood and sexual exposures were reviewed. These included policies and standard operating procedures from emergency departments, occupational health departments, infectious diseases services and community health care settings in Ireland. Guidelines from several UK services were also reviewed. Existing Irish guidelines on immunisation and the prevention of transmission of bloodborne viruses were included in this review. International documents were also examined, e.g. National Institute for Health and Clinical Excellence (NICE) guidelines, Centers for Disease Control and Prevention (CDC) sources and reviews from the Cochrane Database of Systematic Reviews. Information which was deemed relevant for the purpose of developing these guidelines was extracted from these sources by working group members, and then discussed at the working group meetings to ensure that the guidance selected was appropriate for use in various settings throughout Ireland.



In order to provide information for patients and their practitioners on the possible risk of transmission following different exposures, comprehensive reviews of reliable published resources were conducted by the working group members. A new detailed systematic review was not considered necessary, as it was felt by committee members that this would only replicate reviews which have already been published elsewhere, and would not have been feasible within the time allowed for the development of these guidelines. Instead, available published resources were thoroughly reviewed, and their recommendations were appraised by the working group in terms of the reliability of the source, as well as their applicability and operability within Irish healthcare settings.

Where insufficient evidence or guidance was available from these sources, or where there were discrepancies in the information or recommendations from several reliable sources, evidence was sought from original research published in journal articles. Searches were conducted using appropriate MeSH search terms to find the available evidence, and this was further appraised by the working group. The MeSH headings included: hepatitis B; hepatitis B virus; hepatitis C; hepatitis C virus; HIV; transmission; needlestick injuries; bites, human; mucous membrane; sexually transmitted diseases; viral. We searched in MEDLINE, and Embase, and conducted detailed searches in the BMJ, the Lancet, and other core journals relevant to the transmission of HIV, HBV and HCV e.g. AIDS, Clinical Infectious Diseases, Infection Control and Hospital Epidemiology, Occupational Medicine, American Journal of Epidemiology, Journal of the American Dental Association. Articles relating to perinatal or vertical transmission were excluded, as were articles not in English, and articles which were not available in full for review.

A recognised limitation during the development of these guidelines was that, in some areas, clear evidence from research was not available. Where discrepancies or gaps existed in the available guidance and evidence, expert opinion was sought, both from within Ireland, and abroad. For example, in considering the risks from exposure to saliva following an injury such as a human bite, extensive consultation with international oral health experts was conducted.

Consultation

The consultation exercise was carried out as follows:

The draft document was sent to the HPSC SAC in October 2011 and to key stakeholder groups and individuals for consultation in December 2011

The draft document was placed on the HPSC website for general consultation in December 2011. A notice about this posting appeared in the HPSC monthly on-line bulletin, Epi-Insight, in January 2012



The following are the groups to which the draft document was sent for consultation:

Academy of Medical Laboratory Science

An Bord Altranais

Consultants in Emergency Medicine

Consultant Microbiologists

Consultant Paediatricians

Cork University Dental School and Hospital

Department of Health and Children, CMO's office

Directors of Public Health

Dublin Dental University Hospital

Health Information and Quality Authority

Health and Safety Authority

HSE Infection Control Nurses

HSE Integrated Services Directorate

Infection Prevention Society

Infectious Diseases Consultants

Infectious Disease Society of Ireland

Irish Blood Transfusion Service

Irish College of General Practitioners

Irish Dental Association

Irish Faculty of Primary Dental Care

Irish Patients' Association

Irish Prison Service

Irish Society of Clinical Microbiologists

National AIDS Strategy Committee (NASC)

Occupational Health Nurses Association of Ireland

Occupational Medicine Consultants

RCPI Faculty of Occupational Medicine

RCPI Faculty of Paediatrics

RCPI Faculty of Pathology

RCPI Faculty of Public Health Medicine

RCSI Faculty of Dentistry

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Sexual Assault Treatment Units

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Members of the HPSC Scientific Advisory Committee



In developing the EMI guidelines, the working group reviewed existing guidelines that were in use in many healthcare settings throughout the country. The working group would like to thank all those who kindly shared these documents with us and allowed us to use extracts from the documents:

- Beaumont Hospital, Dublin Occupational Health Department
- Cork University Hospital Emergency Department
- · Galway University Hospital Emergency Medicine and Occupational Health Departments
- Garda Siochána Occupational Health Department
- HSE Dublin North East Occupational Health Department
- HSE West (Mid-West) Occupational Health Department
- Mater Misericordiae University Hospital, Dublin Departments of Infectious Diseases, Emergency Medicine, Risk Management, Occupational Health, and Pharmacy
- Our Lady's Children's Hospital, Crumlin Infectious Diseases and Emergency Departments
- Rotunda Hospital, Dublin Sexual Assault Treatment Unit
- St James's Hospital, Dublin GUIDE Clinic and Emergency Medicine, in association with the Gay Men's Health Service, HSE
- St Vincent's University Hospital, Dublin Occupational Health and Emergency Departments
- Waterford Regional Hospital Emergency Department

Guideline Revisions

June 2018

Dolutegravir prescribing information amended regarding pregnancy and women of childbearing potential.

2016

The guidelines were reviewed and where appropriate revised and updated by the HPSC SAC working group and the HSE Sexual Health and Crisis Pregnancy Programme (Dr. Fiona Lyons, Clinical Lead and Ms. Caroline Hurley, Project Manager) in 2016. The revision process was approved by the HPSC SAC. The scope and purpose of the guidelines remain the same.

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Summary of changes:

- 1) Revision of recommendations in relation to the need for HIV PEP following exposure to HIV in the setting of effective antiretroviral therapy
- 2) Inclusion of dolutegravir as an option for HIV PEP
- 3) Increased emphasis on the management of cases following sexual exposure
- 4) Inclusion of Ulipristal Acetate (ellaOne) in the emergency hormonal contraception appendix.

Publication Date: September 2016

Revision Date: September 2018. Interim updates will be made as required.

2014

In 2014 raltegravir replaced Kaletra as the second agent with Truvada for HIV PEP.



Members of the guidelines working group (and organisations they represented)

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Dr Lelia Thornton, Specialist in Public Health Medicine, Health Protection Surveillance Centre (Chair).

Ms Aoibheann O'Malley, Health Protection Surveillance Centre, was administrative secretary to the group.



THE GUIDELINES



THE GUIDELINES

1. Introduction

- 1.1 These guidelines are intended for use in emergency medical settings where a patient first presents with an injury (including needlestick or other sharps injury, sexual exposure, human bite, exposure of broken skin or of mucous membranes) where there is a risk of transmission of infection, in particular bloodborne viruses (BBV). These guidelines are relevant to injuries occurring to members of the public in a community setting and also to injuries sustained occupationally (such as to healthcare workers (HCW) or members of the Garda).
- 1.2 The terms "recipient" and "source" will be used throughout these guidelines:

Recipient: the person who sustains the injury

Source: The source of the potentially infected material, e.g. the person on whom the sharp was used, the person who bites, or the source of the blood or body fluid.

1.3 The BBVs considered in these guidelines are hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

2. Initial assessment

See appendices 1-6:

- Patient management form
- Flow chart for management of injuries
- Algorithm for needlestick/sharps exposure
- Algorithm for mucous membrane exposure
- · Algorithm for sexual exposure
- Algorithm for human bite exposure

Note: If the recipient is a healthcare worker (HCW), they should not manage the incident themselves. Another appropriate health professional should take over responsibility.

2.1 Urgent first aid treatment should be administered if required. Urgent assessment should be made regarding the need for HIV post-exposure prophylaxis (PEP). (See appendix 7 for HIV PEP)

2.2 Initial wound care

2.2.1 For contaminated needlestick injuries, sharps injuries or human bites:

Encourage the wound to bleed.

The recipient should not suck the injury site.

Irrigate the wound thoroughly with running water and soap. A nailbrush should not be used.

Dry, and cover the wound with a waterproof dressing if necessary.

2.2.2 For contamination of the conjunctiva or mucous membranes:

Immediately irrigate the area with copious amounts of normal saline or water. For a splash to the eye, this irrigation should be done before and after removal of contact lenses.

2.2.3 Full clinical assessment should be carried out

Examine for signs of infection, foreign bodies, damage to blood vessels, nerves, tendons, joints or bones (this is particularly important for human bites).

Assess whether the injury has broken the skin.

2.3 Complete the Patient Management Form (appendix 1):

- Document who was injured, how, when and the type of injury.
- Record vaccination status (hepatitis B, tetanus), underlying medical conditions including immunosuppression, medications, and allergies.



2.4 Decide if a significant exposure has occurred.

2.4.1 Assessment of significance of exposure

A significant exposure involves both a high-risk material and a significant injury.

2.4.2 High-risk materials (i.e. significant risk of transmission of BBVs):

Blood, body fluids containing visible blood, semen and vaginal secretions represent a risk of transmission of HBV, HCV or HIV, if the source is infected.¹

(See appendices 21-26 for information about HBV, HCV and HIV)

Outside the body, HCV and HIV significantly decline in infectivity within a few hours. HBV can remain infectious for a week or more.

2.4.3 Low-risk materials (i.e. no significant risk of transmission of BBVs):

Contamination with faeces, nasal secretions, saliva*, sputum, sweat, tears, urine, and vomitus, unless they contain blood, represents a negligible risk of HBV, HCV or HIV transmission.

*If the injury is serious (e.g. extensive or deep tissue bite) HBV transmission may be a risk, even if there is no visible blood in the saliva. In this situation, HBV vaccine with or without HBIG may be indicated (see appendix 6 for algorithm for human bite exposure, appendix 8 for HBV PEP and appendix 18 for discussion of human bite injuries and saliva).

2.4.4 Other materials:

The risk of transmission of BBVs from exposure (e.g. splash) to the following fluids is unknown: Cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, breast milk and amniotic fluid. If the source has a high blood viral load, the viral load in other fluids, such as amniotic fluid, is also likely to be high.

2.4.5 Significant injuries include:

- Percutaneous injuries
- Human bites which break the skin, i.e. involving a breach of the epidermis, not just bruising or indentation of the skin (see appendix 18 for discussion of human bite injuries).
- Exposure of broken skin to blood or body fluids.
- Exposure of mucous membranes (including the eye) to blood or body fluids, e.g. by splashing.
- Sexual exposure (unprotected).

2.4.6 Non-significant injuries include:

- Superficial graze not breaking the skin.
- Exposure of intact, undamaged skin to blood or body fluids.
- Exposure to sterile or uncontaminated sharps.

2.4.7 Non-significant exposure

If the incident involves exposure to a low-risk material or a non-significant injury, no further testing or examination is required. **The patient should be reassured and discharged.** The patient should be given an information leaflet (appendix 27) and a discharge letter (appendix 35) to give to their GP, indicating that no significant exposure occurred, outlining any testing or treatment carried out, and indicating if any follow-on care is needed, such as HBV vaccination or wound care.

The following sections relate only to significant exposures



The remainder of the guidelines relate only to significant exposures

3. Assessing the risk of transmission of infection

3.1 Risk assessment - bloodborne viruses

(See appendices 21 to 26 for information about HBV, HCV and HIV) Where a significant exposure has occurred, a risk assessment should be carried out to estimate the risks of transmission of HBV, HCV and HIV. This should take account of the following:

- The infectious status (HBV, HCV, HIV), if known, of the source.
- If the source is unknown or refuses testing, information may be available about whether the source has risk factors for BBVs (such as: people who inject drugs (PWID), prisoner, commercial sex worker (CSW), men who have sex with men (MSM), born in an endemic country (see appendices 22, 24, 26 for maps), sexual partner with a risk factor).
- Knowledge of the background prevalence of BBVs in the population and in risk groups may be helpful. Knowledge of the prevalence of PWID in the local population may also be helpful.
- The nature of the exposure, including the type of injury and the type of material involved.
- The HBV vaccination status of the recipient.
- The infectious status (HBV, HCV, HIV), if known, of the recipient.

3.2 Factors increasing the risk of transmission of BBV infection:

- Deep percutaneous injuries
- Visible blood on injuring device
- Hollow needle from source patient artery or vein
- · Large bore needle
- Visible blood (of the biter) in mouth of biter
- Blood containing a high viral load of HBV, HCV or HIV
- The presence of HBeAg in source
- Higher volume of material
- Personal protective equipment, e.g. gloves, goggles, not worn (HCWs)
- · Sexual exposure due to aggravated sexual intercourse
- Sexual exposure in men who have sex with men
- Sexual exposure in the presence of concurrent STIs.

3.3 Investigation of source

(See Appendix 29: Checklist: Testing of source person or recipient)

In the case of a significant exposure, every effort should be made to ascertain the HBV, HCV and HIV status of the source.

3.3.1 If the source is known

Where the incident occurred in a hospital and the source is a patient in the hospital, the consultation with the source should be carried out by a member of his/her treating team. When the incident occurred outside the hospital, the consultation and blood testing of the source should be carried out by another suitably qualified health professional e.g. primary care provider, prison healthcare team.



Explain to the source in simple language exactly what has happened.

Ask if they are known to be infected with HBV, HCV or HIV.

Ask if they have risk factors for BBVs, e.g. PWID, CSW, MSM, born in an endemic country (see maps in appendices 22, 24, 26), sexual partner with a risk factor.

- If their BBV status is unknown, request permission from the source, either directly or through their doctor, to take a blood sample for testing for HBV (hepatitis B surface antigen HBsAg), HCV (antibody to hepatitis C anti-HCV) and HIV (HIV antigen/antibody Ag/Ab).
- If the recipient is known to be HBV immune, then the source need not be tested for HBV.
- If the source is HBsAg positive, then hepatitis B e-antigen (HBeAg), antibody to HBeAg (anti-HBe) and HBV viral load should be carried out to estimate the risk of transmission.
- If the source is anti-HCV positive, a HCV ribonucleic acid (RNA) test, and viral load if RNA positive, should be carried out as soon as possible.
- If the source is HIV Ag/Ab positive, a HIV viral load should be done to estimate the risk of transmission.

Where the source is considered likely to be in the window period for a BBV, they should be advised to have repeat testing at 3 months. In such situations, discuss emergency management of the recipient with a HIV/ID specialist, see section 3.4.

Informed consent must be obtained for this testing (see below). Explain why the tests are being done, exactly what tests will be carried out, and the implications for them if a test result is positive. The source must be informed that they are free to refuse to provide a sample or to have this testing carried out. An information leaflet should be provided (appendix 30). If the source refuses consent, this fact should be recorded by the health professional.

The source should be told that the result will be provided by the testing laboratory to their nominated doctor (general practitioner (GP) and/or consultant) and that the recipient will also be told the result. The confidential nature of the testing process should be emphasised. If, as a result of the outcome of this testing, follow-up care is necessary for the source person (e.g. referral to an infectious diseases consultant), this is the responsibility of the hospital consultant if the source is a patient in hospital, or the source person's GP. If the source is not registered with a GP, then it is the responsibility of the doctor who ordered the test to ensure that appropriate follow-up is arranged.

The laboratory should be advised to expect an urgent blood sample and asked to provide the results as soon as possible. The sample may need to be sent by courier. The sample (10mls of clotted blood) should be marked "Urgent. Possible bloodborne virus exposure – source" and should indicate to whom results should be sent with contact details clearly stated. If an RNA test is required, arrangements should be made with the testing laboratory. A second blood sample will be required. Results of source blood tests should be available from the laboratory to allow a decision to be made as soon as possible. In some situations, the urgency with which the blood test is taken and sent to the laboratory is dictated by the circumstances and risk assessment. If a delay is likely and the source is high-risk, consider whether HIV PEP should be started while waiting for the HIV test result. The laboratory should be asked to retain part of the sample for storage for two years.

3.3.2 Informed consent

The components of a legally valid consent are that it must be given by a person with the capacity to consent, it must be given voluntarily and not under any duress or coercion and the person must be given sufficient information to allow them to make a decision. Fully informed consent requires a clinician to disclose to the person the reason for the test or procedure, the benefits and all of the material risks associated with the test or procedure together with the consequences of having or not having the test or procedure and the person understands the information that has been provided, and has been given an opportunity to consider and weigh it up in order to make a decision. Informed consent for HIV testing does not need to include written consent.

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3.3.3 If the source is unknown or known but refuses testing

Assess the risk based on any available information, including the circumstances of the exposure and the epidemiological likelihood of BBV in the source (prevalence of BBVs in the population, known risk environment such as prison, or risk behaviours if source is known). The use of HIV PEP is unlikely to be justified in the majority of such exposures but HBV immunisation may be appropriate, see appendix 7.

Where the source is deemed to be high risk for a BBV and there is likely to be a delay in obtaining consent or results, initiation of HBV immunisation and HIV PEP may be indicated while further information is being obtained. See 4.1.

Consent is required by a clinician who treats, examines, tests or operates on a person and to do so without that person's consent would result in that clinician/ nurse committing an unlawful act. There are exceptions to this principle, usually in exceptional or emergency cases where the treatment is necessary to save the life of or preserve the health of a person. To ensure the greatest level of protection to persons taking samples, where consent is not forthcoming, an application to Court should be made. This can be made at very short notice.

If a blood sample from the source is available to be tested (e.g. it may have been taken for another purpose previously), is it acceptable to test it for bloodborne viruses, even if the source has refused consent or is unconscious or deceased?

Under Irish law, informed consent to testing should be obtained from the source prior to carrying out the test. Where this is not available, the permission of the Court to test should be obtained, save in exceptional circumstances where the treatment is necessary to save the life of or preserve the health of a person and there would not be sufficient time in which to make an application to Court. An application can be made to Court at very short notice.

If a decision is taken to test the sample, the source person should be informed unless to do so would, in the doctor's opinion, be harmful to the individual's mental or physical health.

If the source person is unconscious, is it acceptable to take a blood sample from them for testing?

Under Irish law, informed consent to testing should be obtained from the source prior to carrying out the test. Where this is not available, the permission of the Court to test should be obtained, save in exceptional circumstances where the treatment is necessary to save the life of or preserve the health of a person and there would not be sufficient time in which to make an application to Court. An application can be made to Court at very short notice.

If a sample is taken from an unconscious person, they should be informed as soon as they regain consciousness unless to do so would, in the doctor's opinion, be harmful to the individual's mental or physical health.

If the source person is deceased, is it acceptable to take a blood sample from them for testing?

The position in relation to taking a sample from a deceased person is unclear. If consent from the next of kin is not forthcoming and in order to ensure the greatest level of protection to the person taking a sample, an application should be made to the Court for permission to take the sample. This can be made at very short notice

3.4 Assessing the recipient

(See Appendix 29: Checklist: Testing of source person or recipient)

In the case of a significant exposure:

Obtain details of HBV immunisation status if possible, including number of doses, dates, post-vaccination anti-HBs level.



Ask if they have a HBV vaccination record card (HCWs, Garda and prison personnel are likely to have these).

Ask if they know their infectious status in relation to HBV, HCV or HIV.

Explain why the tests are being done, exactly what tests will be carried out, and the implications for them if a test result is positive.

Informed consent should be obtained and documented before testing is carried out (see 3.3.2). An information leaflet should be provided (appendix 28).

Request HBsAg, antibody to hepatitis B core antigen (anti-HBc), anti-HCV and HIV Ag/Ab. Where there has been sexual exposure request syphilis serology. If the recipient is documented to have an adequate response to HBV vaccine, it is not necessary to test for HBsAg. **See appendix 9 for testing schedule**, including baseline tests and follow-up testing as indicated. See appendix 10 for interpretation of HBV results.

If the recipient was previously vaccinated but the anti-HBs level post-vaccination is unknown, **and** hepatitis B immunoglobulin (HBIG) administration (in addition to vaccine booster) is now being considered, it may be helpful to do an antibody to HBsAg (anti-HBs) test. If the anti-HBs level is ≥10mIU/ml, HBIG is not indicated. If anti-HBs is <10mIU/ml, the result is of no assistance in making the decision about administering HBIG, as antibody level declines over time after vaccination but the person may still be protected due to immune memory. In this situation, assessment of other factors such as the severity of the exposure may assist in making the decision about HBIG (see appendix 8).

Some of the sample should be retained in the laboratory for storage for two years.

If the source tests negative for HBV, HCV and HIV, the recipient can be reassured and testing of the recipient is not required. Where the source tests negative for blood borne viruses but is considered high risk and within the window period, discuss further management with a HIV/ID specialist as soon as possible, ideally within 72 hours. HIV PEP may be indicated in exceptional circumstances.

4. Treatment of recipient following a significant exposure

4.1 The actions to be taken will depend on the outcome of the risk assessment.

If the source blood test results are available and indicate that the source is negative for HBsAg, anti-HCV and HIV Ag/Ab, and the investigation has identified no obvious risk factors for BBVs in the source (i.e. unlikely that source is in window period for infection), then no further follow-up of the recipient is required. They can be reassured and discharged.

However, even if it is deemed that there has been no risk from the current incident, if the recipient has not completed a course of HBV vaccination and may be at risk of HBV infection in the future, they should be encouraged to be vaccinated.

Where the source tests negative for blood borne viruses but is considered high risk and within the window period, discuss further management with a HIV/ID specialist as soon as possible, ideally within 72 hours. HIV PEP may be indicated in exceptional circumstances.

Testing of the source may not be possible or may be delayed. Some actions (below) may need to be taken immediately and without having the results of source testing.



The following actions should be considered when the source is infected or potentially infected with a BBV:

4.2 Hepatitis B post-exposure prophylaxis

Post-exposure, HBV vaccine is highly effective at preventing infection, provided that the vaccine is administered preferably within 48 hours but up to 7 days post-exposure. Due to the safety profile of HBV vaccine and the infectivity of HBV, a low threshold for initiating HBV vaccination is recommended (appendices 8 and 11 – HBV PEP and Hepatitis B vaccine).² In general, HBV vaccination should be offered to all patients who have had a significant exposure, unless they are already immune due to vaccination or past infection. The first dose of vaccine should be given in the health care setting where the person first presents. Give the patient a HBV vaccination record card with the first dose entered (appendix 12). Arrangements should be made for further doses of vaccine to be delivered either by the GP, occupational health service, STI/GUM clinic or infectious diseases clinic as appropriate. If the GP has any queries with regard to such follow-up, they should seek advice from their department of public health or infectious diseases service.

HBIG, in addition to HBV vaccine, may be used in limited circumstances to confer passive immunity after exposure to HBV (appendix 13). HBIG provides short-term protection (3-6 months). HBIG should generally only be given to non-immune patients who have had a significant exposure to a known HBsAg positive patient or to a known non-responder to vaccine who has had exposure to a HBsAg positive source or to an unknown source, following a risk assessment (appendix 8). HBIG should ideally be given within 48 hours of exposure but not later than 1 week after exposure.

The recipient should be tested for HBsAg at baseline, 6 weeks and 3 months (appendix 9).

If the recipient was previously vaccinated, with a documented post-vaccination anti-HBs level of ≥10mIU/ml, they are likely to have long-term protection against HBV infection. No further action is required from the point of view of HBV PEP and no follow-up testing is required (appendix 8).

4.3 Hepatitis C

Currently there is no recommended post-exposure prophylaxis for HCV.³ However, treatment of early infection has been shown to be successful, therefore follow-up monitoring for evidence of HCV infection should be carried out (see appendix 14 for treatment of acute hepatitis C).

If a significant risk of exposure to HCV has occurred, i.e. the source is known or likely to be HCV positive, testing of the recipient for HCV Ag or RNA, and for anti-HCV should be carried out at 6 weeks and 3 months (appendix 9). There is limited data on the performance of HCV Ag testing in the setting of acute HCV infection. It is recommended that you discuss with your local laboratory and ensure that they are aware of the clinical scenario. If the recipient HCV Ag or RNA test is positive, the patient should be referred immediately to an appropriate specialist for assessment.

4.4 HIV post-exposure prophylaxis (See appendix 7 for detailed protocol for HIV PEP)

HIV PEP should only be considered in patients who present within 72 hours with a significant exposure to either a known HIV positive person or a suspected high-risk source, where the overall risk of transmission is >1:1000 (see appendix 7 Table 2).

PEP should not be offered where testing has shown that the source is HIV negative, or if the risk assessment has concluded that HIV infection of the source is unlikely, where the overall risk of transmission is >1:1000 (see appendix 7 Table 2).

If the HIV status of the source is unknown, a careful risk assessment should be carried out. PEP is unlikely to be justified in the majority of such exposures.⁴



If the source is known to be HIV infected and the exposure is significant, see Table 3 Appendix 7 for recommendations on HIV PEP. Where PEP is indicated it should be started as soon as possible, ideally within an hour of exposure. PEP should not be offered if more than 72 hours has elapsed since the exposure. A 3-5 day starter pack of antiretroviral medications should be supplied to the patient. An urgent referral should be arranged to an appropriate clinician specialising in HIV treatment or a clinician with significant experience in managing HIV PEP. Ensure that the first appointment is scheduled before the finish of the PEP starter pack. An information leaflet should be given to the patient (appendix 31). All emergency departments and occupational health departments should have arrangements in place for timely access to starter packs of PEP. Where there is concern about information from the source in relation to HIV treatment or presence of resistance virus the source's HIV physician or a HIV specialist should be consulted as soon as possible, and within 72 hours. The total duration of HIV PEP is 28 days.

Local arrangements should be put in place so that relevant information on the source can be made available to the clinician caring for the recipient.

PEP should be discontinued immediately if a HIV test on the source is found to be negative (unless the risk assessment indicates that there is a high likelihood that the source is in the window period and on the advice of a HIV/ID specialist).

4.5 Tetanus

Depending on the circumstances of the injury, tetanus immunisation should be considered. See appendix 15 re risk assessment for the use of tetanus vaccine and tetanus immunoglobulin (TIG).

4.6 Antibiotic treatment

Prophylactic antibiotics are not routinely recommended for needlestick injuries, although each wound should be assessed individually. Antibiotic prophylaxis is indicated after human bites, especially to the hand (see appendices 6 and 18).

5. Specific injuries and settings

5.1 Occupational exposure

See appendices 3 and 4 for algorithms for management of needlestick and mucous membrane exposures, and appendix 17 for discussion of occupational exposure.

5.2 Sexual exposure

If a sexual assault has occurred, the recipient should be offered referral to the nearest sexual assault treatment unit (SATU) for further management.

In cases of sexual exposure which do not involve assault, the following actions should be taken in the emergency department:

- Assess the need for HIV PEP (see above and appendix 7)
- Offer HBV vaccination unless known to be immune. Consider HBIG (see appendix 8)
- Take blood for baseline BBV testing (see appendix 9), including syphilis
- Consider emergency contraception (appendix 16) and give information leaflet (appendix 32)
- Advise safe sex (i.e. condoms) for 3 months
- Arrange follow-up within 3-5 days in ID/genitourinary medicine (GUM) clinic or with other appropriate HIV treating clinician if HIV PEP starter pack commenced
- Give the recipient an information leaflet (appendix 33)
- Refer to sexually transmitted infection (STI)/GUM clinic in 2 weeks time (appendix 34)

See appendix 5 for algorithm for management of sexual exposure.



5.3 Human bites

Following a human bite, an individual risk assessment is required, taking account of the extent of the injury, the HBV immunisation status of the recipient and the BBV status of the source and the recipient. With the exception of a deep bite wound sustained from a source who is infected or has risk factors for HBV, in a recipient who is not HBV immune, the risk of BBV transmission is negligible. A recipient of a bite that breaches the skin but with no visible source blood does not require any follow-up from the point of view of HIV and HCV.

HBV vaccination should be advised for an unvaccinated recipient following a percutaneous or mucous membrane exposure to saliva from a source who is HBV infected or high-risk but of unknown sero-status (see appendix 8). HBIG may also be indicated, depending on the risk assessment, but generally only if the source is HBV positive. HIV PEP would almost never be indicated except in extreme circumstances.

See appendix 6 for algorithm for management of human bites and appendix 18 for a detailed discussion of the risks of human bites.

5.4 Community acquired needlestick injury

Injuries from discarded needles and syringes in public places create considerable anxiety regarding the possible transmission of bloodborne pathogens. While these injuries pose less of a risk than that resulting from a needlestick injury in health-care settings, the perception of risk often results in the necessity for evaluation, testing and counselling of the injured person. Management of such injuries includes acute wound care and consideration of the need for prophylactic management, based on a detailed risk assessment.

HBV is the most stable of the major bloodborne viral pathogens and can survive in the environment for 1 week or longer. It is advisable to administer a full course of HBV vaccine to those susceptible to HBV infection. HBIG is not usually required unless the needle comes from a known HBV positive source and a risk assessment identifies a significant risk of HBV transmission (appendix 8). The likelihood of transmission of other bloodborne viruses such as HCV or HIV is very remote.²

In general PEP for HIV is not recommended but should be considered in high-risk situations – based on location (e.g. prisons) and likely source (e.g. PWID, insulin injection), the presence of fresh blood, the amount of blood, the type of needle involved (e.g. large bore, hollow), and depth of penetration. 5,6,7

See appendix 3 for algorithm for needlestick/sharps exposure and appendix 19 for a detailed review of community needlestick injuries.

5.5 Injury in dental practice

Protocols should be in place in the dental setting to prevent avoidable exposures and to minimise risk. These protocols should include the safe use of equipment, the use of personal protective equipment, training, re-training and induction, the need for vaccination, the need for documentary evidence of immunity and what to do in case of an accident. A responsible person should be appointed to manage such incidents. It is vitally important that the practice identifies in advance an appropriate unit to which to refer an injured person. The legislation which covers this area is the Safety, Health and Welfare at Work Act 2005 (and 2007 Regulations).

Emergency management of an injury

- 1. Immediate wound hygiene should be carried out.
- If a significant exposure has occurred, i.e. a bite, or an injury from a used needle or from a used sharp, immediate referral should take place to the appropriate unit (emergency department or infectious disease specialist or occupational health specialist) where a definitive risk assessment is carried out.
- 3. The management of the recipient (injured party) is directly based on risk assessment of the source. The information to assist the appropriate unit in making this assessment should be provided by the practice using the On-Site Assessment Form (appendix 20) which is downloadable from the IDA website (www.dentist.ie). Copies of this form should be readily available in all practices to facilitate speedy referral.



- 4. The source must be informed before they leave the practice that an injury has occurred and the On-Site Assessment Form should be completed in their presence. The source should be asked if they have any relevant medical history or risk factors for bloodborne viruses. They should be asked if their medical history and contact phone number can be passed on to the medical team that will treat the recipient. The source should also be informed that they may be contacted by the recipient's treating doctors and asked to provide a blood test. They should be reassured that all information will be treated with strict confidentiality by the recipient's treating doctors, and that where necessary appropriate follow-up care will be offered to them. The source should be informed that the results of their blood tests may have to be disclosed to the recipient.
- 5. The use of information put on the On-Site Assessment Form must comply with data protection legislation.
- 6. Contact details of the responsible person (from the dental practice) both during and after hours must be made available to the appropriate unit.

5.6 Injury in primary care medical practice

The management of injuries in the primary care medical practice setting should be dealt with broadly along the same lines as in a dental practice. Where there is relevant expertise within a medical practice then it may be more appropriate to deal with the injury and follow-up within that practice.

6. Information and follow-up of recipient

6.1 Information

All recipients, whether or not the exposure is significant, should receive appropriate information. If no significant exposure has occurred, no follow-up is required and no precautions need be taken. The patient should be reassured, given an information leaflet and discharged (appendix 27).

If a significant exposure has occurred, the recipient should receive information about the level of risk, the testing required, the implications of a positive result, the implications of treatment, the precautions required and the arrangements for follow-up. An information leaflet should be given (appendix 28). If the recipient has particular concerns, formal counselling may be arranged.

6.2 Precautions

If a significant exposure has occurred, the recipient should be advised to take certain precautions, depending on the exposure and actions taken:

- Adopt safe sex practices (i.e. use condoms) for 3 months
- If planning to donate blood, tissue, breast milk, sperm or organs, the person should inform the relevant donation agency about the exposure incident and follow their recommendations
- Seek expert advice regarding pregnancy or breast-feeding
- In the absence of infection, healthcare and other workers need not be subject to any modification of their work practices
- No restrictions are necessary in relation to participation in contact sports
- Do not share toothbrushes, razors or needles

These precautions should be outlined in written form, e.g. a leaflet (appendix 28).

6.3 Follow-up

Where a significant exposure has occurred, follow-up may be required for the following:

- · Blood tests and feedback of results
- Monitoring for clinical evidence of HBV, HCV or HIV infection. If evidence of infection occurs, an urgent referral should be made to an appropriate specialist.
- Completion of HBV vaccination course
- HIV PEP
- Ongoing counselling
- STI screen



Arrangements should be made for follow-up by the appropriate service and the recipient clearly advised about this. This will depend on the circumstances of the incident and the type of injury.

If the person has been started on HIV PEP, they should be monitored by a clinician specialising in HIV treatment or a clinician with significant experience in managing HIV PEP. An urgent referral should be made to ensure that they are first seen by this specialist before the starter pack of antiretroviral medication is finished. The referral pathway to this specialist should be clearly defined in each region and a written note given to the patient clearly stating where they should go (appendices 31, 34).

For recipients not prescribed HIV PEP:

- Healthcare staff who have received an occupational injury should be referred to their occupational health department for follow-up. If they have no occupational health department, they should go to their own GP for follow-up if required (appendix 35).
- Members of the public should be referred to their own GP, an STI/ID/GUM/SATU service or their own occupational health service (appendix 35).

7. Records/documentation

7.1 Patient management form

All parts of the patient management form should be completed (appendix 1) and the form retained in the service where the consultation took place.

7.2 Recording of medication

Details of all medications prescribed, administered and supplied (e.g. PEP, antibiotics, vaccines) should be recorded in the appropriate patient record (e.g. hospital chart, occupational health department medical record). For vaccines and immunoglobulin products, the batch number and expiry date should be recorded.

7.3 Notifiable diseases

HBV, HCV and HIV are notifiable diseases and should be notified by the attending doctor to the director of public health (DPH)/medical officer of health (MOH) (see appendix 36 re details of DPHs). A notification form may be downloaded from: http://www.hpsc.ie/hpsc/NotifiableDiseases/NotificationForms/

7.4 Occupational exposures

If the injury occurred in the workplace setting, the appropriate report forms should be completed and management informed.

If, as a result of a work related injury, the employee is absent from work for more than 3 consecutive days, the employer must report the injury using the IR1 form available from the Health and Safety Authority (HSA).

Under the Safety, Health and Welfare at Work (Biological Agents) Regulations 1994 and amendment Regulations 1998, the employer must inform the HSA of any work related accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection/human illness e.g. a percutaneous injury with a contaminated sharp where the source patient is known or found to be positive for hepatitis B, hepatitis C or HIV. The IR3 Report of Dangerous Occurrence Form may be used to report the incident to the HSA, available at www.hsa.ie.

7.5 Risk management forms for hospital

Where the injury relates to an incident that occurred in a hospital setting, appropriate risk management forms should be completed.



References

(Additional references may be found at the end of some appendices)

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Glossary of abbreviations and terms

Abbreviations

Ab Antibody Ag Antigen

AIDS Acquired Immunodeficiency Syndrome

ALT Alanine aminotransferase

Anti-HBc Antibody to hepatitis B core antigen
Anti-HBe Antibody to hepatitis B e antigen

Anti-HBs Antibody to hepatitis B surface antigen

Anti-HCV Antibody to hepatitis C virus

BBV Bloodborne virus. e.g. HIV, HBV, HCV
CANSI Community acquired needlestick injury

CDC Centers for Disease Control and Prevention (Atlanta, USA)

CSW Commercial sex worker

DTaP Diphtheria, tetanus and acellular pertussis vaccine

DPH Director of public health
DNA Deoxyribonucleic acid

ECDC European Centre for Disease Prevention and Control

EIA Enzyme-linked immunoassay
EPP Exposure-prone procedure

EU European Union
GP General practitioner
GUM Genitourinary medicine

HAART Highly active antiretroviral therapy

HBeAg Hepatitis B e antigen

HBIG Hepatitis B specific immunoglobulin

HBsAg Hepatitis B surface antigen

HBV Hepatitis B virus

HCC Hepatocellular carcinoma

HCV Hepatitis C virus
HCW Healthcare worker

Hib Haemophilus influenzae b

HIV Human immunodeficiency virus

HPSC Health Protection Surveillance Centre

HSE Health Service Executive

IBTS Irish Blood Transfusion Service

ICGP Irish College of General Practitioners

ID Infectious diseases

IPV Inactivated polio virus vaccine

IM Intramuscular
 IU International units
 MOH Medical officer of health
 MSM Men who have sex with men
 n/a not available; not applicable



PEP

NIAC National Immunisation Advisory Committee

NICE National Institute for Health and Clinical Excellence

NVRL National Virus Reference Laboratory
 OHD Occupational Health Department
 OHP Occupational Health Physician
 PCR Polymerase chain reaction

PEPSE Post-exposure prophylaxis for sexual exposure

Post-exposure prophylaxis

PWID People/person who injects drugs
RCPI Royal College of Physicians of Ireland

RNA Ribonucleic acid
ROI Republic of Ireland

SATU Sexual Assault Treatment Unit
STD Sexually transmitted disease
STI Sexually transmitted infection
SVR Sustained virological response
Td Tetanus, low-dose diphtheria

Tdap Tetanus, low dose diphtheria and low-dose acellular pertussis vaccine

TIG Tetanus immunoglobulin

UNAIDS Joint United Nations Programme on HIV/AIDS

UPSI Unprotected sexual intercourse
WHO World Health Organization



Terms

- Endemic: The constant presence of a disease or infectious agent within a given geographic area or population group; may also refer to the usual prevalence of a given disease within such area or group.
- Exposure incident: A specific exposure to the eye, mouth, other mucous membrane, nonintact skin, or parenteral exposure to blood or other potentially infectious materials. Examples of an exposure incident include blood spattering into the eyes, splashing into the mouth or a puncture by a blood-contaminated needle.
- Fight bite: A fight bite or closed fist injury is a laceration to the "knuckle" (MCP joint) of the hand of someone who punches another person in the mouth.
- Parenteral: Piercing the skin barrier or mucous membranes e.g. by needlestick.
- Percutaneous: An exposure through the skin (e.g. a needlestick or cut with a sharp object)
 or contact of non-intact skin (e.g. exposed skin that is chapped, abraded, or afflicted with
 dermatitis) with blood, tissue, or other body fluids that are potentially infectious.
- Post-exposure prophylaxis (PEP): The administration of a drug to prevent the development
 of an infection after the patient has been exposed to the infection, e.g. HIV PEP involves
 administration of antiretroviral drugs to HIV-negative persons who have been exposed to HIV in
 an effort to prevent establishment of infection. HBV PEP involves the administration of hepatitis
 B vaccine and/or hepatitis B specific immunoglobulin after exposure.
- Recipient: The person who sustains the injury. In the case of a bloodborne virus exposure incident, the recipient is exposed to blood or body fluids of someone else, who is known as the source.
- Risk factors: An aspect of personal behaviour or lifestyle, an environmental exposure, or an inborn or inherited characteristic that is associated with an increased occurrence of disease.
- Seroprevalence: The level of a pathogen in a population, as measured in blood serum.
- Sharps: Any items that have the potential to puncture the skin and inoculate the recipient with infectious material.
- Source individual: The source of the potentially infectious material, e.g. the person on whom the sharp was used, the person who bites, or the source of the blood or body fluid.
- Standard Precautions: Standard Precautions are the minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is delivered. Standard Precautions include: 1) hand hygiene, 2) use of personal protective equipment (e.g. gloves, gowns, masks), 3) safe injection practices, 4) safe handling of potentially contaminated equipment or surfaces in the patient environment, and 5) respiratory hygiene/cough etiquette.
- Sustained virological response (SVR) (for hepatitis C treatment): The absence of detectable hepatitis C RNA in the serum as shown by a qualitative hepatitis C RNA assay with lower limit of detection of 50 IU/ml or less at 24 weeks after the end of treatment.
- Toxoid: is a modified bacterial toxin that has been rendered non-toxic but has the ability to stimulate the formation of antitoxin.
- Window period: The time interval after infection during which serological assays for antigen and/or antibody are negative.



APPENDICES



Bloodborne Virus Exposure • Patie	ent Management Form
Reporting time::	Reporting date:
Doctor name:	Doctor signature:
RECI	PIENT DETAILS Past Medical History (incl. immunosuppression)
Name	Tast Medicat History (med. minianosuppression)
Address	
	Is recipient known to have HBV, HCV, or HIV? No Yes Detail below
Gender M G F Date of birth/	
Tel no. Mobile	Medications
Occupation	Allergies
Work address	If female Pregnant Breastfeeding
100000000000000000000000000000000000000	Hepatitis B Vaccination
GP name and address and telephone number	1 dose 2 doses Full course Year
	Tetanus
	Date of last vaccination Number of doses
ASSESSMEN	IT OF EXPOSURE RISK
Details of injury (date, time, place etc.)	[n n n n n n n n n n n n n n n n n n n
	Needlestick/sharp injury Hollow bore needle Solid Needle
	Visible blood present
	Device had been directly in source artery or vein Other sharp Describe
	Severity of needlestick or sharp injury
	Superficial - source scratch, no blood appeared
	Moderate - penetrated skin and blood appeared Deep - puncture, with or without blood appearance
	Human bite Skin breached
	Splash Intact skin Non-intact skin
	Mucous membrane Eye
	Sexual exposure
Nature of material (e.g. blood, saliva, semen etc.)	Receptive anal Insertive anal
	Receptive oral Insertive oral
	Receptive vaginal Insertive vaginal
	Condom used/ condom intact Ejaculated
if NOT blood, was fluid blood stained Yes No	If sexual assault, consider referral to a sexual assault treatment
	unit or social worker
	Other injury (describe in "Details of injury" box)
HEALTHCARE EXPOSURES (Consider using local form if applicable)	Instrument (if any) which caused the injury
Area where exposure occured	What was the instrument originally intended for?
Was this an 'exposure prone procedure'? Yes No	Did the instrument have a sefety week misure? Ver
Were gloves worn at the time of the injury? Yes No	Did the instrument have a safety mechanism? Yes No Was the safety mechanism activated? Yes No
	Table Salety meetianism derivated . Tes 140



DECI: Overall, is exposure significant? (see section 2	
If no, no further follow up is required Reassured Patient information leaflet provided (appendix 27) Discharged	If exposure is considered significant, proceed. If unsure how to proceed, discuss with senior doctor in the Emergency Department or in Infectious Diseases.
If exposure is considered significant Is source known? Yes No e.g. source hosp (Health care institution to assign an ID number by which the recipient and	oital MRN or laboratory number nd source can be confidentially linked)
RECIPIENT MANAG	EMENT CHECKLIST
First aid given Yes No (see section 2) Recipient bloods taken (appendix 9) Yes No Appropriately labeled "Possible BBV exposure - Recipient" Test Date Result HBsAg Anti-HBc Anti-HCV HIV Ag/Ab Syphilis (sexual exposures only) Pregnancy Informed consent received for testing Yes No (see Checklist, appendix 29)	Treatment record, including PEP HBV vaccination given (appendices 8 & 11) HBIG required (appendix 8) HBIG given HIV PEP offered (appendix 7) HIV PEP accepted (HIV PEP should be discontinued immediately if the source is found to be HIV negative) Considered interactions between PEP and other medication (Consult BNF, pharmacist, www.hiv-druginteractions.org, product insert) HIV PEP information leaflet given (appendix 31) Baseline bloods taken (FBC, LFTs, Renal, Bone profile) Urinalysis for proteinuria (in renal impairment, give first dose of Truvada and discuss with an ID consultant. Isentress can be given) Time between exposure and starting HIV PEP hours Number of days of HIV PEP given days HIV PEP drugs prescribed (name of drugs) Tetanus vaccine given (appendix 15)
Social worker referral Sexual assault unit referral Emergency contraception Garda notification if patient agrees	Tetanus immunoglobulin (TIG) Examined wound for infection Antibiotics prescribed Note: Record details of medication/ vaccines in patient's chart
FOLLOW-UP AR	PRANCEMENTS
Precautions advised during follow-up period – 3 months (appendix 28) Avoid unprotected sexual practices Seek expert advice regarding pregnancy or breastfeeding Discussed Compliance with medication Possible adverse reactions and how to manage them No modification to work practices	Follow-up referral for: (Please use the standard referral forms— appendices 34 & 35) Test results Further testing (6/52, 3/12) (appendix 9) Vaccinations HIV PEP (urgent, in 3-5 days — appointment to be arranged in ID or HIV clinic, or in the occupational health department (if appropriate)).
No restrictions to sports Importance of advising relevant agency if donating blood, blood products, organ donation, other donation	Counselling STI screen Patient information leaflet regarding significant exposures provided (appendix 28)



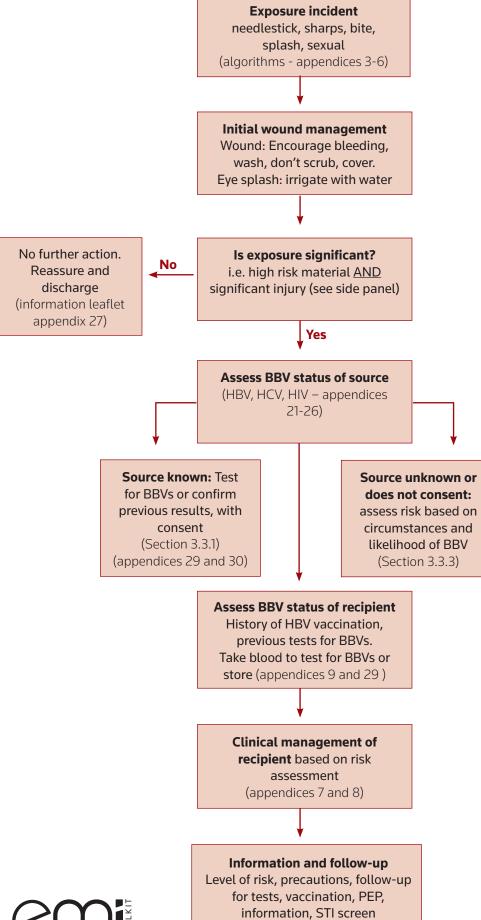
INFORMATION ON SOURCE



			1001
Do not give this part of the form to the recipient if it contains confidential information that the recipient has not themselves provided.			
	l MRN or laboratory number	nt is being referred	I
(Health care institution to assign an ID number by which the recipient	and source can be confidentially linked)		
ASSESSMENT OF SOURC	E INFECTIVITY (SEE SECTION 3.3)	
Source: Any risk factors for BBV? Yes No No	Unknown		
PWID Prisoner			
Born in an endemic country (Refer to maps in appendices 22, 24, 26)			
Recipient of blood/ blood products (pre August 1973 H	BV, pre Oct 1985 HIV, pre Oct 1991 HCV)		
High risk sexual behaviour			
MSM (men who have sex with men			
CSW (commercial sex worker)			
Multiple sexual partners			
Partner with BBV			
Is source immunosuppressed? Yes No Unknown	If unknown serology, test the following:	Date sent	Result:
HBV	HBsAg		
HBsAg: Positive Negative Unknown	If HBsAg positive: HBeAg		<u></u>
If positive: HBeAg positive Viral load	Anti-HBe Viral load		<u></u>
If negative: Date of last negative test	viiat toau		
HCV	Anti-HCV		
Anti-HCV: Positive Negative Unknown	If Anti-HCV positive: RNA		
If positive: RNA positive Viral load	Viral load		
If negative: Date of last negative test			
HIV	HIV Ag/Ab		
HIV Ag/Ab: Positive Negative Unknown	If HIV Ag or Ab positive: Viral load		
If positive: Viral load CD4 count			
What ART now?			
If negative: Date of last negative test			
Was source consent received for testing? Ye	s No		
Implications of testing discussed with source Yes No			
Consent sought from source to disclose test results to recipient Yes No			
Source information leaflet provided (appendix 30)	s No		
Reason for not testing source person serology (if applicable)			
Unknown source Refused	Dead Unable to give consent U		
Discharged/ not available Next of kin not available			



Management of injuries where there is risk of bloodborne virus (BBV) transmission



(information leaflet appendix 28)

High risk materials:

blood, semen, vaginal secretions, body fluids with visible blood

Low risk materials:

urine, nasal secretions, saliva*, sputum, faeces, vomit, sweat, tears – unless visible blood

Significant injury:

percutaneous, human bite* with skin broken, exposure of broken skin or mucous membrane to blood or body fluids, sexual exposure (unprotected)

*If human bite with no visible blood, only risk is HBV.

Non-significant injury:

superficial graze, exposure of intact skin, exposure to sterile sharps

Source testing:

HBsAg, anti-HCV, HIV Ag/ Ab. If HBsAg positive, test HBeAg, anti-HBe and viral load. If anti-HCV positive, test HCV RNA and viral load. If HIV positive, test viral load

Recipient testing:

HBsAg, anti-HBc, anti-HCV, HIV Ag/Ab, ±anti-HBs

Clinical management

of recipient may include: HBV PEP (vaccine ± HBIG); HIV PEP; Emergency contraception; tetanus; antibiotics

Follow-up/referral may be:

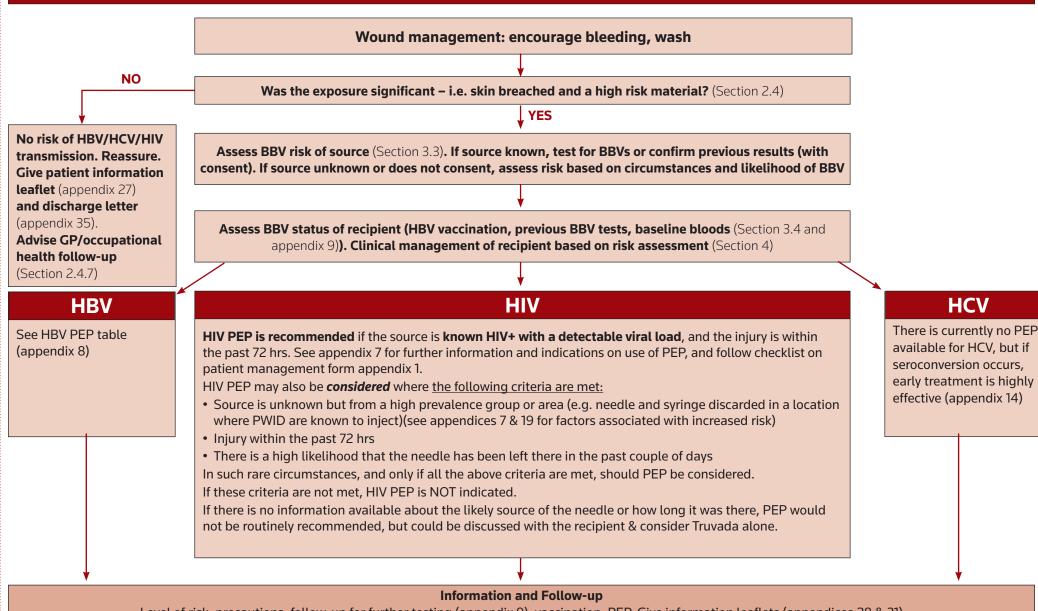
GP, Occupational Health, ID, SATU, STI/GUM



Management of BBV risk following exposure to needlestick/sharps in occupational (appendix 17) or community setting (appendix 19)



Complete patient management form (appendix 1)



Level of risk, precautions, follow-up for further testing (appendix 9), vaccination, PEP. Give information leaflets (appendices 28 & 31)

(appendix 35).

(appendix 8)

health follow-up

HBV

Management of BBV risk following exposure of mucous membrane or broken skin in occupational or community setting Complete patient management form (appendix 1) Wound (or eye, mouth) irrigation NO Was the fluid a high risk material? (Section 2.4) YES No risk of HBV/HCV/HIV Assess BBV risk of source (Section 3.3). If source known, test for BBVs or confirm previous results (with transmission. Reassure. consent). If source unknown or does not consent, assess risk based on circumstances and likelihood of BBV **Give patient information leaflet** (appendix 27) and discharge letter Assess BBV status of recipient (HBV vaccination, previous BBV tests, baseline bloods Advise GP/occupational (Section 3.4 & appendix 9). Clinical management of recipient based on risk assessment (Section 4) HIV **HCV** See HBV PEP table There is currently no PEP HIV PEP should only be **considered** where the following criteria are met: available for HCV, but if • Injury within the past 72 hours seroconversion occurs, • Splash from high risk material to non-intact skin, eye or mouth early treatment is highly • Source is known HIV-positive with a detectable viral load effective (appendix 14) If these criteria are not met, HIV PEP is NOT indicated See appendix 7 (HIV PEP)

Information and Follow-up

Management of BBV risk following sexual exposure

Complete BBV patient management form (appendix 1)

Consider need for emergency contraception (appendix 16) / SATU referral (appendix 36) / risk of other STIs

NO

Was the exposure significant? (i.e. exposure to blood/semen/vaginal secretions)

No risk of HBV/HCV/HIV transmission. Reassure. No further follow-up required. Give patient info leaflet (appendix 27) and discharge to GP (appendix 35)

Assess BBV risk of source (Section 3.3). If source known, test for BBVs or confirm previous results with consent. If source unknown or does not consent, consider if high risk group e.g. PWID/MSM/CSW/endemic country (Section 3.1)

Assess BBV status of recipient (HBV vaccination, previous BBV tests, baseline bloods (Section 3.4 and appendix 9)) **Clinical management of recipient based on risk assessment** (Section 4)

HBV

See HBV PEP table (appendix 8)

> Follow appendix 7 for details on HIV PEP and use the management checklist in the patient management form (appendix 1). Outside of these recommendations, HIV PEP should not be prescribed without discussion with an ID/HIV specialist, where it may be considered in rare extreme cases.

Source HIV status

Do not give/consider PFP if more than 72 hours since the exposure

Do not give/consider FEF in more than 72 mours since the exposure					
	HIV positive		Unknown HIV status		
EXPOSURE TYPE	HIV VL unknown/ detectable	HIV VL undetectable	From high prevalence country / risk-group	From low prevalence country / group	
RECEPTIVE ANAL SEX	RECOMMENDED	NOT RECOMMENDED Provided source has confirmed HIV VL<200c/ml for >6 months	RECOMMENDED	NOT RECOMMENDED	
INSERTIVE ANAL SEX	RECOMMENDED	NOT RECOMMENDED	CONSIDER*	NOT RECOMMENDED	
RECEPTIVE VAGINAL SEX	RECOMMENDED	NOT RECOMMENDED	CONSIDER*	NOT RECOMMENDED	
INSERTIVE VAGINAL SEX	CONSIDER [®]	NOT RECOMMENDED	CONSIDER*	NOT RECOMMENDED	
FELLATIO WITH EJACULATION	NOT RECOMMENDED	NOT RECOMMENDED	NOT RECOMMENDED	NOT RECOMMENDED	
FELLATIO WITHOUT EJACULATION	NOT RECOMMENDED	NOT RECOMMENDED	NOT RECOMMENDED	NOT RECOMMENDED	
SPLASH OF SEMEN INTO EYE	NOT RECOMMENDED	NOT RECOMMENDED	NOT RECOMMENDED	NOT RECOMMENDED	
CUNNILINGUS	NOT RECOMMENDED	NOT RECOMMENDED	NOT RECOMMENDED	NOT RECOMMENDED	

^{*} Prevalence of HIV within communities may change these recommendations from consider to recommend in areas/groups of particular high HIV prevalence

Information and Follow-up

Ensure patient is clear about follow-up plan. Advise regarding safer sex until after the window period. Give written information (appendices 28 & 33).

HCV

There is currently no PEP available for HCV. but if seroconversion occurs, early treatment is highly effective (appendix 14)

⁸ Where source HIV viral load is high (e.g. recent seroconversion) or where there is evidence of genital ulceration

Management of BBV risk following human bite breaching skin – or 'fight bite' (closed fist injury-see appendix 18) There is no risk of BBV transmission if the skin is not breached. Complete BBV patient management form (appendix 1)



Follow-up

HCV and HIV

required for HBV,

YES

Oral antibiotic (Augmentin if not penicillin allergic) + wound irrigation (If 'fight bite' – refer for washout) + tetanus prophylaxis (appendix 15)

No risk of HCV/HIV transmission. No further follow-up required for HCV or HIV. HBV follow-up as per HBV PEP table (appendix 8) as it is theoretically possible that HBV can be transmitted through a deep tissue bloodless bite. Manage as per table and patient will need HBsAg (but not HIV/HCV) level at 6 weeks and 3 months if not HBV immune.

NO

Was biter (source) bleeding from mouth prior to bite?

Consider risk to biter if bitten person's blood gets in biter's mouth

Assess BBV risk of source (Section 3.3). If source known, test for BBVs or confirm previous results (with consent).

If source unknown or does not consent, is it likely that they are from a high risk group e.g. PWID/MSM/CSW/endemic country (Section 3.1)?

To date there have only been a handful of reports of BBV transmission from human bites and few of these were convincing. All cases involved deep bites where there was blood in the mouth of the biter, and where the biter had high viral loads. Thus the absolute risk is not known - deemed to be possible but extremely rare.

Assess BBV status of recipient (HBV vaccination, previous BBV tests, baseline bloods (Section 3.4 and appendix 9))

Clinical management of recipient based on risk assessment (Section 4)

HBV

See Hepatitis B PEP table (Appendix 8).

HIV

HIV PEP should only be prescribed where all the following criteria are met:

- 1. It is within 72 hours of the injury
- 2. There was deep tissue injury
- 3. The biter was, with complete certainty, bleeding from their mouth prior to the bite
- 4. The biter is known to be HIV positive and is either not on ART or not virologically suppressed on ART. Where the biter is on ART with an undetectable viral load for >/= 6 months, PEP is NOT indicated.

If all 4 criteria are met, HIV PEP is indicated. Follow the management steps for HIV PEP prescription as outlined in the management checklist on the patient management form (appendix 1), and in appendix 7 (HIV PEP). Outside of this, HIV PEP should not be prescribed without discussion with an ID/HIV specialist, where it may be considered in rare extreme cases.

Information and Follow-up

Level of risk, precautions, follow-up for further testing (appendix 9), vaccination, PEP. Give information leaflets (appendices 28 & 31)

HCV

There is currently no PEP available for HCV, but if seroconversion occurs, early treatment is highly effective (appendix 14)



HIV POST-EXPOSURE PROPHYLAXIS (PEP)

Key points

- 1. Only consider PEP if within 72 hours of exposure
- 2. The first dose of PEP should be given as soon as possible within 2 hours if possible
- 3. Assess risk based on type of exposure and what is known about source (consider risk of HBV and HCV also see relevant appendices)
- 4. Test source if feasible
- 5. Discuss with senior doctor in emergency medicine or HIV specialist if unsure how to proceed
- 6. If PEP indicated:
 - a. Counsel
 - b. Test blood and urine
 - c. Prescribe starter pack
 - d. Arrange follow up at ID or GUM clinic before starter pack runs out
 - e. Advise no unprotected sex for 3 months
- 7. Complete the patient management form (appendix 1) it will serve as a checklist

Introduction

The use of post-exposure prophylaxis (PEP) against HIV infection dates back to the early 1990s, when only limited antiviral treatment for chronic infection was available. Prophylaxis was primarily used after occupational exposures.¹ A case-control study published in 1997 showed that health care workers who received zidovudine after needlestick exposures were 81% less likely to undergo seroconversion to positivity for HIV.² Generally, combination therapies are prescribed nowadays, so current HIV PEP may be more effective. However, PEP is not a guarantee of protection.

After exposure to HIV through sexual contact or injecting drug use, antiretroviral therapy may also be administered for prophylaxis against infection. No efficacy data are available for this strategy, but substantial safety and feasibility data have led to its widespread acceptance.¹

General principles

HIV PEP should only be considered in patients who present within 72 hours with a significant exposure from either a known HIV positive person or a suspected high risk source. The first dose of PEP should be given as soon as possible - within 2 hours if possible.

PEP should not be offered where testing has shown that the source is HIV negative, or if the risk assessment has concluded that HIV infection of the source is unlikely.

If the HIV status of the source is unknown, a careful risk assessment should be carried out. PEP is unlikely to be justified in the majority of such exposures.³

Risk assessment

The risk of an individual acquiring HIV following an exposure is dependent upon the risk that the source is HIV-positive where unknown, and the risk of infection following a specific exposure from an HIV-positive individual.⁴

Risk of HIV transmission = risk that source is HIV-positive x risk of exposure* (*including co-factors such as sexually transmitted infections, high HIV viral load and bleeding).⁴



Table 1 Risk of HIV transmission per exposure from a known HIV-positive individual not on ART

(Adapted from BASHH UK Guideline for use of HIV PEPSE 20154 – source references omitted from table)

Type of exposure	Estimated risk of HIV transmission per exposure from a known HIV-positive individual not on ART
Receptive anal intercourse	1 in 90
Receptive anal intercourse with ejaculation	1 in 65
Receptive anal intercourse no ejaculation	1 in 170
Insertive anal intercourse	1 in 666
Insertive anal intercourse not circumcised	1 in 161
Insertive anal intercourse and circumcised	1 in 909
Receptive vaginal intercourse	1 in 1000
Insertive vaginal intercourse	1 in 1,219
Semen splash to eye	<1 in 10,000
Receptive oral sex (giving fellatio)	<1 in 10,000
Insertive oral sex (receiving fellatio)	<1 in 10,000
Blood transfusion (one unit)	1 in 1
Needlestick injury	1 in 333
Sharing injecting equipment (includes chemsex)	1 in 149
Human bite	<1 in 10,000

NB: All sexually related risk probabilities are for unprotected sexual exposure; it is assumed similar risks will exist where condom failure has occurred

The table above is simply a guide. There are a number of factors that may increase the risk of transmission such as high viral load in the source, and intercurrent STIs, e.g. syphilis.

The overall number of HIV cases in the UK diagnosed in HCWs following occupational exposures is five documented cases and 31 probable cases, eight of these probable cases being diagnosed prior to 1997.⁵

Table 2 Estimated risk of HIV transmission by type of exposure where source HIV status is unknown

Type of exposure	Population group (% HIV prevalence)	Risk of HIV transmission - source HIV status unknown	Rounded off estimated risk per exposure (compared with risk if source known HIV+)
Receptive anal sex MSM*	MSM in Ireland (8%) ⁶	8/100 x 1/90 = 1/1125	1/1000 (1/90)
Insertive anal sex MSM*	MSM in Ireland (8%) ⁶	8/100 x 1/666 = 1/8325 (overall) 8/100 x 1/161 = 1/2012 (not circumcised)	1/8000 (1/666) 1/2000 (1/161)
Receptive oral sex MSM*	MSM in Ireland (8%) ⁶	8/100 x 1/10,000 = 1/125,000	1/100,000 (<1/10,000)
Receptive vaginal sex	Heterosexuals in Ireland (0.15%) ^{7,%}	0.15/100 x 1/1000 = 1/666,666	1/700,000 (1/1000)
NSI [†] from unknown non high risk hospital pt	Heterosexuals in Ireland (0.15%) ^{7,%}	0.15/100 x 1/333 = 1/222,000	1/200,000 (1/333)
NSI [†] from community source	PWID [‡] in Ireland (5 to10%) ^{8,9,§,&}	5/100 x 1/333 = 1/6660 to 10/100 x 1/333 = 1/3330	1/7000 to 1/3000 (1/333)

^{*}MSM=men who have sex with men

^{*}Of note, the prevalence of diagnosed HIV varies geographically in Ireland with crude prevalence of 2.0/1000 amongst 17-78 year olds in Dublin. (Patients Accessing Ambulatory Care for HIV-infection: Epidemiology and Prevalence Assessment. Tuite H et al. Ir Med J. 2015 Jul-Aug;108(7):199-202).

[†]NSI=needlestick injury

^{*}PWID=people who inject drugs

[§]Personal communications: Dr Shay Keating, Drug Treatment Centre Board and Dr Jean Long, Alcohol and Drug Research Unit, Health Research Board.

[&]Of note there has been an increase in the number of recent HIV infections diagnosed amongst PWID in Dublin (http://www.hpsc.ie/A-Z/HIVSTIs/HIVandAIDS/HIVPeoplewhoinjectdrugs/MainBody,15231,en.html)



It is generally recommended that HIV PEP is only offered when the estimated transmission risk is 1 in 1000 or greater, but all cases are considered on a case-by-case basis. PEP can be considered in those with a risk of between 1 in 1,000 and 1 in 10,000 only in very exceptional circumstances.

Table 3 HIV PEP recommendations by type of exposure and source status

(Adapted from BASHH UK Guideline 2015^4 – modified to take account of higher prevalence of HIV in PWID population in Ireland compared to UK. The last two rows are not contained in the BASHH Guideline table)

	Source HIV status				
	HIV po	sitive	Unknown HIV Status		
	HIV VL unknown / detectable	HIV VL undetectable	From high prevalence country / risk-group*	From low prevalence country / group	
Receptive anal sex	Recommend	Not recommended ^{&} Provided source has confirmed HIV VL<200c/ml for >6 months	Recommend	Not recommended	
Insertive anal sex	Recommend	Not recommended ^{&}	Consider [†]	Not recommended	
Receptive vaginal sex	Recommend	Not recommended ^{&}	Consider [†]	Not recommended	
Insertive vaginal sex	Consider [%]	Not recommended ^{&}	Consider [†]	Not recommended	
Fellatio with ejaculation ‡	Not recommended**	Not recommended	Not recommended	Not recommended	
Fellatio without ejaculation [‡]	Not recommended	Not recommended	Not recommended	Not recommended	
Splash of semen into eye	Not recommended	Not recommended	Not recommended	Not recommended	
Cunnilingus	Not recommended	Not recommended	Not recommended	Not recommended	
Sharing of injecting equipment	Recommend	Not recommended	Consider [†]	Not recommended	
Human bite [§]	Consider in very limited circumstances*** (see Bite algorithm, appendix 6)	Not recommended	Not recommended	Not recommended	
Needlestick from a discarded needle in the community			Consider in very limited circumstances*** (see Needlestick/Sharps algorithm, appendix 3)	Not recommended	
Needlestick direct from source***	Recommend	Not recommended	Consider [†]	Not recommended	
Blood splash to non-intact skin, eye or mouth***	Consider	Not recommended	Not recommended	Not recommended	

^{*}High prevalence groups within this recommendation are those where there is a significant likelihood of the source individual being HIV-positive. Within Ireland at present, this is likely to be men who have sex with men, and individuals who have immigrated from areas of high HIV prevalence (particularly sub-Saharan Africa) (See map of global HIV prevalence, appendix 26)

Estimating probability that source is HIV positive

In the case of a significant exposure, every effort should be made to ascertain the HIV status of the source.

If the source is known, the exposure should be outlined to the source and consent requested for blood to test for HIV Ag/Ab (and HBsAg, anti-HBc and anti-HCV)(appendices 29 & 30).

- The source is considered HIV negative if there is a recent HIV negative result within the past 3 months plus no clinical indication of a retroviral/ seroconversion-like illness, and source is not considered to be at high risk of infection.
- The source is considered HIV positive if they have a positive HIV result, or a physician has diagnosed HIV or the source self-reports a diagnosis of HIV. A low or undetectable HIV viral load greatly diminishes but does not completely eliminate the risk of transmission. PEP should be discussed with the treating ID consultant if the source is on anti HIV medication. If not contactable, commence standard PEP.

If the exposure involves a source person with either unknown HIV status or unknown identity it is not possible to give reassurance that the risk of HIV infection is zero. However, it may be possible to estimate risk, e.g. is the source from a high risk group such as PWID, MSM or from a country of high prevalence.

[&]amp; Provided source's HIV viral load is undetectable for >/= 6 months. Where there is uncertainty about results or medication adherence, PEP

^{&#}x27;More detailed knowledge of local prevalence of HIV within communities may change these recommendations from *consider* to *recommend* in areas/groups of particularly high HIV prevalence

^{*}Where source HIV viral load is high (e.g. recent seroconversion) or where there is evidence of genital ulceration

^{*}PEP is not recommended for individuals receiving fellatio, i.e. inserting their penis into another's oral cavity

^{**}Consider where recent seroconversion or evidence of oropharyngeal ulceration or trauma.

[§]A bite is assumed to constitute breakage of the skin with passage of blood

^{***}Denotes parts of table that differ from BASHH Guideline



(See appendices 25 & 26 on HIV epidemiology and risk of transmission, and maps of global HIV prevalence and prevalence in PWID).

Counselling

If the risk of HIV is estimated to be high and PEP is being considered, the recipient should receive counselling on the risks and benefits of PEP. The counselling should cover:

- The estimated HIV risk
- The potentially serious adverse reactions to PEP which must be balanced against the risk of HIV infection
- The possible requirement to inform insurer of a positive test result, as is applicable for an existing policy or for a new application
- The benefits of early identification versus the implications of a positive result
- The window period.

Give the recipient an information leaflet about significant exposures (appendix 28).

Decision not to give PEP

If PEP is not to be given, explain why. Arrange for follow-up to be carried out by a GP, occupational health service or STI clinic as appropriate (appendix 35).

Decision to give PEP

If a decision is taken to prescribe PEP, the recipient should be advised:

- · How to take the medication
- The importance of adhering to the prescribed medication
- The expected side effects
- That only a starter pack is being prescribed.

Give the recipient a HIV PEP information leaflet (appendix 31)

Baseline investigations of recipient prior to prescribing HIV PEP

Baseline investigations prior to prescribing PEP are outlined in table 4. Blood samples should be labelled "Possible BBV exposure – recipient".

Table 4 Baseline recipient investigations prior to prescribing PEP

Safety bloods	FBC, U&E, LFTs, Bone profile	Must be reviewed
Pregnancy test	Urine strip	prior to discharge
Urinalysis	Dipstick for proteinuria	home
HIV testing	HIV Ag/Ab	
Hepatitis	HBsAg, anti-HBc, anti-HCV	
Syphilis	If sexual exposure	

Prescribing HIV PEP

Key points

- Discuss with senior doctor in emergency medicine or infectious diseases if unsure how to proceed.
- Only start PEP within 72 hours of the risk event.
- The first dose of PEP should be given as soon as possible within 2 hours if possible. It is not necessary to wait for blood results on the recipient (table 4) or the source.
- Ensure baseline safety bloods are within normal limits before discharge. If there is renal impairment or proteinuria, see special prescribing situations below.
- In general, dolutegravir should not be used in early pregnancy or in women of childbearing potential.
- PEP should be discontinued immediately if a HIV test on the source is found to be negative, unless the source is at high risk of recent infection, in which case, continuation of PEP should only be on the explicit advice of a HIV physician.
- It is important to note that antiretrovirals are unlicensed in Ireland for PEP. However, there are no licensed alternatives and they are widely used internationally and accepted as best practice.

Drug-drug Interactions

Overall the drugs chosen for HIV PEP pose a relatively low risk for drug-drug interactions but as with all prescribing, complete a full medication history (including herbal remedies, vitamins/minerals, over the counter medicines and recreational drugs) before prescribing HIV PEP.



Truvada: There are no significant drug-drug interactions with Truvada.

Raltegravir: Advise patient to stop antacids and multivitamins (products containing metal cations e.g. magnesium/ aluminium, which can reduce the absorption of raltegravir) during PEP. Prescribe a PPI/H2 antagonist if required.

Increase the dose of raltegravir to 800mg 12 hourly if co-administration with rifampicin is required. Other cytochrome P450 inducers can be used with the standard dose of raltegravir.

Dolutegravir: Advise patients to take calcium and iron supplements, multivitamins and aluminium and magnesium containing antacids (which reduce the absorption of dolutegravir) at least 2 hours after or 6 hours before Dolutegravir.

Increase the dose of dolutegravir to 50mg 12 hourly if co-administration with rifampicin, phenytoin, phenobarbital, carbamazepine, oxcarbazepine or St. John's Wort is required.

Dolutegravir increases the concentration of metformin and a dose adjustment should be considered when starting and stopping dolutegravir to maintain glycaemic control.

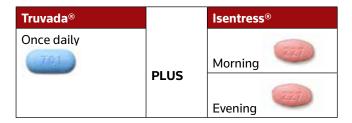
Dolutegravir is contra-indicated with dofetilide due to potential life-threatening toxicity caused by high dofetilide concentrations.

Additional resources include the product insert for the drug, the British National Formularly, www.hiv-druginteractions.org and www.medicines.ie.

Medications - Adults

Standard 3-5 day Starter Pack (ED/SATU):

Truvada® (tenofovir/emtricitabine) one blue tablet daily, plus Isentress® 400mg (raltegravir) 1 pink tablet twice daily, a total of 3 tablets/day.



Truvada® should be taken with food as this improves tenofovir absorption and may reduce nausea. If patients have difficulty in swallowing, Truvada® can be dispersed in approximately 100ml of water or orange juice and taken immediately. Isentress® tablets however, should be swallowed whole and not chewed, broken or crushed (Isentress® SmPC, www.medicines.ie)

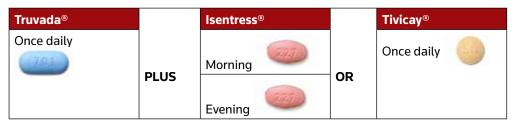
All medications must be reviewed by an ID/HIV specialist or a clinician with significant experience in managing HIV PEP before the starter pack runs out. A leaflet explaining the contents of the pack, the possible side effects and brief advice on how to deal with them should be provided to the patient (appendix 31).

Standard Regimen STI/ID clinic:

Truvada® (tenofovir/emtricitabine) one blue tablet daily, plus Isentress® 400mg (raltegravir) 1 pink tablet twice daily, a total of 3 tablets/day.

Or (Note: In general, dolutegravir is not recommended in early pregnancy or in women of childbearing potential)

Truvada® (tenofovir/emtricitabine) one blue tablet daily, plus Tivicay® 50mg (dolutegravir) one yellow tablet once daily, a total of 2 tablets/day. (Dolutegravir with tenofovir disoproxil fumarate-emtricitabine as HIV post-exposure prophylaxis in gay and bisexual men. McAllister J et al. Available at http://programme.aids2016.org/Abstract/Abstract/1203)



Patients who have been started on the standard starter pack, may continue on this regimen to complete the 4 weeks of treatment or may have the Isentress® switched to Tivicay® when they attend the ID/HIV or STI clinic for follow-up. The decision will be dictated by a number of factors, including potential drug-drug interactions between Tivicay® and other concomitant medications.



Truvada® should be taken with food as this improves tenofovir absorption and may reduce nausea. If patients have difficulty in swallowing, Truvada® can be dispersed in approximately 100ml of water or orange juice and taken immediately. Isentress® tablets, however should be swallowed whole and not chewed, broken or crushed. Tivicay® can be taken with or without food.

Potential Side Effects:

Truvada® and Isentress®: GI side effects are common. Headache is common. Severe side effects are uncommon, but include rash, renal impairment and hepatoxicity. Patients experiencing side effects should contact their doctor. Tivicay®: Headache, dizziness and GI disturbance are reported as very common side effects. Insomnia, abnormal dreams, depression, rash, pruritus, elevations in ALT and CK are reported as common side effects. Patients experiencing side effects should contact their doctor. Further information on dosing and potential side effects and drug-drug interactions can be found in the relevant summary of product characteristics (Truvada® SmPC, Isentress® SmPC and Tivicay® SmPC all available at www.medicines.ie)

Special Prescribing situations

- Source is known to be HIV positive and on antiretroviral drugs: Discuss with ID/HIV specialist. If not contactable, commence standard starter pack and ensure follow up with ID/HIV specialist urgently.
- 2. Renal impairment or proteinuria: Give first dose of Truvada® and discuss with ID/HIV specialist regarding the need for dose adjustment. Isentress®can be given. Tivicay® may alter creatinine excretion leading to an increase in serum creatinine but does not cause renal impairment or need to be dose adjusted in renal impairment.
- 3. Pregnancy: If indicated, commence same PEP. In general, dolutegravir is not recommended in early pregnancy or in women of childbearing potential. Ensure urgent specialist follow up
- 4. Breastfeeding: Breastfeeding is generally not recommended while taking PEP. If the patient is currently breastfeeding or considering breastfeeding, this should be discussed with an obstetrician or an ID/HIV specialist.
- 5. Patients unable to tolerate 3-drug PEP: In exceptional circumstances the regimen can be switched to Truvada® alone. This should always be discussed first with an ID/HIV specialist.

Precautions

Advise the recipient to adopt safe sex practices (i.e. use condoms) for 3 months. See section 6.2 of main guidelines regarding precautions.

Follow-up

A recipient started on HIV PEP should be monitored by a clinician specialising in HIV treatment or a clinician with significant experience in managing HIV PEP. An urgent referral should be made to ensure that this visit takes place before the starter pack runs out (appendix 34). Note: Starter packs are not used in paediatrics. The doctor should complete the patient management form (appendix 1). This will serve as a referral form for the specialist clinic. Follow-up arrangements should be recorded in the patient's notes.

Medications - Children

(Adapted from Post Exposure Prophylaxis (PEP) Guidelines for children and adolescents potentially exposed to HIV. Our lady's Children's Hospital, Crumlin, February 2016)

The risk assessment should be as per adults. The treatment is outlined below.

Counsel and advise the family, and provide information leaflets outlining side effects of medication.

- 1. Young people from 10 years of age and over 35Kg who are able to swallow tablets should receive PEP as for adults: Raltegravir 400mg (Isentress®) 1 tablet twice daily + Truvada® 1 tablet daily.
- 2. Young people 10 years of age or older with renal insufficiency should not receive Tenofovir and should therefore be given: Raltegravir 400mg (Isentress®) 1 tablet twice daily + fixed dose combination of Lamivudine 150mg/Zidovudine 300mg (Combivir®) 1 tablet twice daily.
- 3. Tenofovir TDF should be avoided in the context of renal impairment at any age if at all possible (seek expert advice).
- 4. Although Raltegravir is currently licensed in children younger than 6 years and weighing>11Kg, experience of use in children in this age group is limited. Kaletra® remains an alternative in children under 6 years of age with chewable Raltegravir as first line. (seek expert advice).



Regimens

Accurate weight and height measurements should be used to calculate doses. Surface area calculation:

$$BSA(m^2) = \sqrt{\frac{weight(kg) \times height(cm)}{3600}}$$

Paediatric starter packs are not in use and not recommended as drugs are dispensed according to the individual's body surface area. It is recommended that all centres with paediatric units should have paediatric HIV PEP preparations in stock or have formal arrangements in place whereby the drugs can be promptly sourced from another centre.

Table 5 Suggested PEP regimens¹⁰ (see dosing Table 2 below)

Age (years)	Preferred PEP	Alternative PEP	Notes
10+	Raltegravir (Isentress®) + Truvada® (emtrictabine 200mg / tenofovir disoproxil fumarate (TDF) 300mg NB if under 35KG, we would recommend age and weight appropriate dosing of raltegravir + TDF + Lamivudine	1. Raltegravir (Isentress®) + Lamividune 150mg/ Zidovudine 300mg (Combivir®) combined tablet	As per adult guideline with an alternative for Tenofovir in those with renal insufficiency
6-9	Raltegravir (Isentress®) + Lamivudine (Epivir®) + Zidovudine (Retrovir®)	1. Kaletra® (lopinavir/Ritonavir) + Lamivudine (Epivir®) + Zidovudine (Retrovir®) 2. Raltegravir (Isentress®) or Kaletra® (Lopinavir/Ritonavir) + Tenofovir TDF (Viread®) + Lamivudine (Epivir®)	Adult dose of Raltegravir for children >25Kg. Note the chewable formulation of raltegravir is not bioequivalent to the tablets (See table of preparations available below)
2- <6	Raltegravir (Isentress®) + Lamivudine (Epivir®) + Zidovudine (Retrovir®)	1. Kaletra® (Lopinavir/Ritonavir) + Lamivudine (Epivir®) + Zidovudine (Retrovir®) 2. Raltegravir (Isentress®) or Kaletra® (Lopinavir/Ritonavir) + Tenofovir TDF + Lamivudine (Epivir®)	Use Raltegravir (Isentress® chewable tablets) when available
<2	Kaletra® (Lopinavir/Ritonavir) + Lamivudine (Epivir®) + Zidovudine (Retrovir®)		Liquid formulations



Table 6: HIV PEP Drugs, Doses and Side Effects¹⁰

Dosing is correct as per date of guideline publication but for updated dosing see CHIVA ART dosing table http://www.chiva.org.uk/ Generally, medicines are well tolerated with the exception of minor, initial gastrointestinal disturbance and possible headache.

Drug	Formulation	Dose	Potential Side Effects*
Raltegravir (RAL) (Isentress®)	Tablet: 400mg	Tablet: From 25Kg 400mg BD	Rash, nausea, hepatitis
Note: Formulations are not bioequivalent; use chewable tablets for children 11-25Kg and children >25Kg who cannot swallow tablets	Chewable Tablet: 25mg, 100mg (can be chewed or swallowed)	Chewable Tablet: 11-14Kg: 75mg BD 14-20Kg: 100mg BD 20-28Kg: 150mg BD 28-40Kg: 200mg BD >40Kg: 300mg BD Take with or without food.	
Zidovudine (AZT, ZDV) (Retrovir®)	Capsule:100mg Liquid:10mg/mL	Capsule or liquid: 180mg/m²/Dose BD to a maximum dose of 250mg BD (max. 300mg BD when used in combination products) Preferably on an empty stomach. If nausea occurs can be taken with food.	Granulocytopenia and/or anaemia, nausea, headache, myopathy, hepatitis, neuropathy
Lamivudine (3TC)	Tablet: 150mg	Tablet or Liquid:	Peripheral neuropathy,
(Epivir®)	Liquid: 10mg/mL	4mg/Kg/dose BD to a maximum of 150mg BD Take with or without food.	nausea, diarrhoea, headache
Truvada®	Combined tablet:	Combined tablet:	Headache nausea,
Do not use if known renal impairment	(Tenofovir TDF 300mg / Emtricitabine FTC 200mg)	>35Kg: 1 tablet daily	vomiting, diarrhoea, renal tubular, dysfunction bone demineralization
Tenofovir TDF (Viread®)	Tablet TDF (TD)	Tablet:	Do not use if known renal impairment
	300mg (245mg)	>35Kg: 1 tablet daily	impairment
Note: 300mg Tenofovir disoproxil fumarate (TDF) = 245mg Tenofovir disoproxil (TD)	For paediatric use: the tablet: TDF (TD) 300mg	2-12 years: 8mg (6.5mg)/Kg once daily	
All doses expressed as TDF	(245mg) disperses in 10mL water within 5 minutes	10-12Kg: 80mg(66mg)= 2.7mL 12-14Kg: 100mg(83mg)= 3.4mL 14-17Kg:120mg(99mg)= 4mL	
Continued: Tenofovir TDF (Viread®) Note: 300mg Tenofovir disoproxil fumarate = 245mg Tenofovir disoproxil (TD) All does expressed as TDF(TD)	Tablet: TDF (TD) 300mg (245mg) For paediatric use: the tablet: TDF (TD) 300mg (245mg) disperses in 10mL water within 5 minutes	Continued: 17-19Kg:14Omg(116mg)= 4.7mL 19-22Kg:16Omg(132mg)= 5.4mL 22-24Kg: 18Omg(149mg)= 6.1mL 24-27Kg: 20Omg(165mg)= 6.7mL 27-29Kg: 22Omg(182mg)= 7.4mL 29-32Kg: 24Omg(198mg)=8.1mL 32-34Kg: 26Omg(215mg)= 8.8mL 34-35Kg: 28Omg(231mg)= 9.4mL ≥35Kg: 30Omg(245mg)= 10mL The dose can be diluted in orange juice	Do not use if known renal impairment
Combivir®	Combined tablet:	to improve taste Combined tablet:	As for ZDV and 3TC
Complyif	Lamivudine 150mg (3TC) / Zidovudine (ZDV) 300mg	>30Kg: 1 tablet twice daily	AS for ZDV and STC
Kaletra®	Liquid:	Liquid:	Diarrhoea, abdominal pain,
2 adult tablets = 4 paediatric tablets = 5mL of liquid	Lopinavir (LPV) 80mg/ Ritonavir (RTV) 20mg per mL	300mg/m²/dose BD Dose in mls = (300 x BSA) / 80	nausea, vomiting, headache
All doses are based on Lopinavir (LPV)	Paediatric tablet: (pale yellow)	Paediatric tablet: 15-25Kg: 2 tablets BD	
	Lopinavir (LPV)100mg/ Ritonavir (RTV) 25mg	25-35Kg: 3 Tablets BD	
	Adult tablet: (yellow) Lopinavir (LPV)200mg/	>35Kg: 4 Tablets BD Adult tablet: >35Kg: 2 Tablets BD	
	Ritonavir (RTV) 50mg		

^{*}This list of side effects is not exhaustive – refer to product datasheet for detailed information on side effects, interactions with other medicines and other cautions for use.



References

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Hepatitis B post-exposure prophylaxis

Hepatitis B vaccine is highly effective in preventing acute infection after exposure if given within 7 days and preferably within 48 hours.

Hepatitis B immunoglobulin (HBIG) is only indicated where the source is known HBsAg positive, or where the recipient is a known non-responder to HBV vaccine and the source is known to be high risk. HBIG should ideally be given within 48 hours but not later than 7 days after exposure.

Exposure type	 Needlestick injury Bite with breach of skin Sexual exposure Mucosal exposure to bloo 	d or body fluids containing bloo	od		
Recipient vaccination status	Recipient unvaccinated against HBV	Recipient not fully vaccinated against HBV (<3 doses)	Recipient fully vaccinated against HBV but anti-HBs unknown ⁴	Recipient documented non- responder to HBV vaccine	Recipient known responder to HBV vaccine, i.e. anti-HBs≥10 mIU/ml
Source known to be HBsAg positive	Give HBIG ¹ Start accelerated ² HBV vaccine course Recommend vaccination be completed	Give HBV vaccine dose. Test recipient anti-HBs urgently Consider HBIG¹if <10 mIU/ml (Urgent consult to ID/GUM specialist) Recommend vaccination be completed	Give HBV vaccine dose. Test recipient anti-HBs urgently Consider HBIG¹ if <10 mIU/ml (Urgent consult to ID/GUM specialist)	Give HBIG¹ plus HBV vaccine dose Urgent ID/GUM referral for alternative vaccination strategy	No need for further vaccine dose
Source HBV status unknown but potential high risk, ie from country of high or intermediate prevalence ³	Make every effort to test source Start accelerated ² HBV vaccine course Recommend vaccination be completed	Make every effort to test source Give HBV vaccine dose Recommend vaccination be completed	Make every effort to test source Give HBV vaccine dose	Make every effort to test source Give HBV vaccine dose Consider HBIG¹ (Urgent consult to ID/GUM specialist) Urgent ID/GUM referral for alternative vaccination strategy	No need for further vaccine dose
Source HBV status unknown - no high risk features, ie normal population risk ⁵	Start accelerated ² HBV vaccine course Recommend vaccination be completed	Give HBV vaccine dose Recommend vaccination be completed	Give HBV vaccine dose	Make every effort to test source Give HBV vaccine dose Urgent ID/GUM referral for alternative vaccination strategy	No need for further vaccine dose
Source HBsAg negative	Routine (opportunistic) HBV vaccination course	Routine (opportunistic) HBV vaccination course	No need for further vaccine dose	Routine ID/GUM referral for alternative vaccination strategy	No need for further vaccine dose

¹For bite with no visible blood, risk assess or seek urgent ID specialist advice re giving HBIG

²An accelerated vaccine course consists of doses at 0, 1 and 2 months. A booster dose is given at 12 months to those at continuing risk. The standard course is 0, 1 and 6 months.

³Africa, Asia, Central and South America, Central and Eastern Europe. Refer to CDC map: http://wwwnc.cdc.gov/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/hepatitis-b.htm or appendices 21 & 22

⁴ If the recipient was fully vaccinated as an infant, no further testing or booster dose of HBV vaccine is required. Universal infant HBV vaccination commenced in Ireland in September 2008.

⁵ People who inject drugs in Ireland have only a 2% risk of being HBsAg positive and are thus not considered to be high risk. The prevalence in the general population is ≤0.1%



TESTING OF RECIPIENT

- This section does not cover testing of the recipient for the purpose of monitoring HIV PEP treatment.
- 2. If a significant exposure has occurred, BBV testing of the recipient at baseline and over a period of follow-up is indicated. If no significant exposure has occurred, then no recipient testing is required.
- 3. If test results on the source are available and show that the source is negative for HBV, HCV and HIV, and the source is not considered to be at high-risk for recent infection, then testing of the recipient is not required.
- 4. Informed consent should be obtained from the recipient before any testing is carried out (appendices 28 & 29).
- 5. Baseline testing is to reflect the recipient's current status not to test for infection related to the current exposure.

Testing of recipient where a significant exposure has occurred			
Time of test	Status of source		
	 BBV status unknown <u>OR</u> Negative but high-risk <u>OR</u> Positive for HBV, HCV or HIV 	Negative for HBV, HCV and HIV <u>AND</u> not high- risk	
Baseline	HBsAg [†] Anti-HBc Anti-HCV HIV Ag/Ab For sexual exposure Syphilis serology	Follow up testing is not required but baseline testing may be offered in an opportunistic way.	
2 weeks	STI testing for sexual exposures		
6 weeks	HBsAg [†] Anti-HCV HCV Ag or RNA [*] HIV Ag/Ab For sexual exposure Syphilis serology		
3 months	HBsAg [†] Anti-HCV HCV Ag or RNA HIV Ag/Ab For sexual exposure Syphilis serology		

[†] If recipient documented to have an adequate response to HBV vaccine, it is not necessary to test for HBsAg *Liaise with local lab in relation to whether Ag or RNA testing is being performed and ensure that the laboratory is aware of the clinical scenario

Anti-HBs testing:

If the recipient was previously vaccinated but anti-HBs level post-vaccination is unknown, \underline{and} HBIG administration (in addition to vaccine booster) is now being considered, it may be helpful to do an anti-HBs test at baseline. If the anti-HBs is ≥ 10 mIU/ml, HBIG is not indicated. If anti-HBs is ≤ 10 mIU/ml, the result is of no assistance in making the decision about administering HBIG, as antibody level declines over time after vaccination but the person may still be protected due to immune memory. In this situation, assessment of other factors such as the severity of the exposure may assist in making the decision about HBIG.

If recipient initiates a course of HBV vaccination, an anti-HBs test should be carried out 2 months after completion of the course of vaccination.

Sample and accompanying information

For serology samples 10mls of clotted blood is required. Where RNA testing is also being performed, an EDTA sample may be required. Please check with your laboratory what type of



sample is required and if there is a requirement to deliver samples within a timeframe from time of collection. The request form should include the following information:

- Label: "Possible BBV exposure recipient"
- Test and retain for 2 years
- List the tests requested (as per table)
- Give the details and contact number (preferably mobile number) of the healthcare professional to whom the results should be sent

Negative test results

If all these tests are negative, no further testing is needed.

Positive test results

If any of the test results are positive, a referral to an appropriate specialist should be made (appendix 34).

Testing of needles

Testing of needles or sharps for the presence of BBVs is not recommended.



INTERPRETATION OF HBV RESULTS (Adapted from Immunisation Guidelines for Ireland. 2013 Edition. Chapter 9 - Hepatitis B, updated September 2015.

National Immunisation Advisory Committee, RCPI)

HBsAg	<u>HBeAg</u>	Anti-HBe	Anti-HBc lgM	Anti-HBc total	Anti-HBs	Interpretation
Neg	Neg	Neg	Neg	Neg	Neg	Susceptible to HBV
POS	POS	Neg	POS/Neg	POS/Neg	Neg	Acute HBV infection
Neg	Neg	Neg	POS	POS ¹	Neg	Recent HBV infection (HBsAg window)
POS	POS	Neg	WEAK POS/ Neg	POS	Neg	Chronic HBV infection ²
POS	Neg	POS/Neg	WEAK POS/ Neg	POS	Neg	HBeAg neg chronic HBV infection ³
Neg	Neg	POS/Neg	Neg	POS*	POS/Neg	Resolved HBV infection
Neg	Neg	Neg	Neg	Neg	<u>POS</u>	Response to hepatitis B vaccine

Notes

¹Anti-HBc detected in two assays

² Follow up sample required to confirm chronic HBV infection

³ Follow up sample required and also HBV DNA viral investigations may be required



HEPATITIS B VACCINE

HBV vaccine contains recombinant HBsAg, derived from yeast cells, adsorbed onto aluminium hydroxide adjuvant. The vaccine is effective at preventing infection in individuals who produce specific antibodies to HBsAg (anti-HBs). However, around 10-15% of adults fail to respond or have a poor response to 3 doses of vaccine. Poor response is associated with age over 40 years, male gender, obesity and smoking. Lower seroconversion rates have also been reported in those with alcoholic liver disease. Patients who are immunocompromised or have chronic renal failure may respond less well and may require larger or more frequent doses of vaccine.

HBV vaccine is used for pre-exposure and post-exposure protection and provides long-term protection.

Pre-exposure prophylaxis: Since 2008, all infants are offered HBV vaccine as part of the routine childhood immunisation schedule at 2, 4 and 6 months of age. In addition, HBV vaccine is recommended for those who are at increased risk of infection because of their occupation, close contact with cases, medical conditions, or lifestyle factors such as injecting drug use, and sexual behaviour.

Vaccine efficacy studies have shown that 90-100% of vaccinated persons who develop anti-HBs ≥10mIU/ml after a primary series are protected from HBV infection.

Post-exposure: HBV vaccine is highly effective at preventing infection, provided that the vaccine is administered preferably within 48 hours but up to 7 days post-exposure.

Specific hepatitis B immunoglobulin (HBIG) is available for passive protection and, when indicated, is normally used in combination with HBV vaccine to confer passive/active immunity after exposure. It should be administered according to the manufacturer's guidelines and should ideally be given within 48 hours of exposure but not later than a week after exposure. HBIG provides short-term protection (3-6 months) (see appendix 13)

Schedule and dosage:

The basic HBV immunisation schedule consists of three doses of vaccine at 0, 1 and 6 months. Alternative accelerated schedules exist (e.g. 0, 1 and 2 months; 0, 7 and 21 days – see manufacturer's guidelines) if more rapid protection is required. These should be followed by a dose of vaccine at 12 months to complete the course.

Currently licensed vaccines contain different concentrations of antigen. The appropriate manufacturer's dosage should be adhered to. Higher doses of vaccine should be used for adult patients with chronic renal failure, and considered for other immunosuppressed adults.

Administration: The vaccine is given intramuscularly in the deltoid region and not in the gluteal region. In the case of infants, the vaccine may be given in the anterolateral thigh.

Contraindications: The vaccine is contraindicated in a person who has had an anaphylactic reaction to preceding doses of a HBV-containing vaccine or any of its constituents.

Pregnancy and breastfeeding: Pregnancy is not a contraindication to HBV vaccination. No adverse effect on the developing foetus has been observed when pregnant women have been immunised against HBV. Breastfeeding is not a contraindication to HBV immunisation.



Adverse reactions: HBV vaccine is generally well tolerated. The commonest reactions are soreness and redness at the injection site. Fever, rash, malaise and influenza-like symptoms are less commonly reported after vaccination.

Post-vaccination testing: Routine post-vaccination testing for anti-HBs is recommended 2 months after completing the course of vaccination for persons who are at continuing risk of HBV exposure. Following primary vaccination, it is preferable to achieve anti-HBs levels above 100mIU/ml although levels above 10mIU/ml are generally accepted as protecting against infection. Anti-HBs titre often declines post-vaccination but a rapid anamnestic response develops after exposure to the virus.

Reference



HEPATITIS B VACCINATION PATIENT RECORD CARD

Patient Record Card	Patient Record Card
Please keep safe and bring card with you for hospital appointments Patient MRN:	Please keep safe and bring card with you for hospital appointments Patient MRN:
Patient Name:	Patient Name:
Healthcare Facility:	Healthcare Facility:
Vaccine 1 Date: Next vaccine dose due:	Vaccine 1 Date: Next vaccine dose due:
Vaccine 2 Date: Next vaccine dose due:	Vaccine 2 Date: Next vaccine dose due:
Vaccine 3 Date:	Vaccine 3 Date:
Return for Blood Test on:	Return for Blood Test on:
Post Vaccination Anti-HBs Titre Level:	Post Vaccination Anti-HBs Titre Level:
It is important that all doses of vaccine are administered	It is important that all doses of vaccine are administered
Patient Record Card	Patient Record Card
Please keep safe and bring card with you for hospital appointments	Please keep safe and bring card with you for hospital appointments
Patient MRN:	Patient MRN:
Patient Name:	Patient Name:
Healthcare Facility:	Healthcare Facility:
Vaccine 1 Date: Next vaccine dose due:	Vaccine 1 Date: Next vaccine dose due:
Vaccine 2 Date:	Vaccine 2 Date:
Next vaccine dose due:	Next vaccine dose due:
Vaccine 3 Date:	Vaccine 3 Date:
Return for Blood Test on:	
	Return for Blood Test on:
Post Vaccination Anti-HBs Titre Level:	Post Vaccination Anti-HBs Titre Level:

A downloadable version of this card can be found at www.emitoolkit.ie



HEPATITIS B IMMUNOGLOBULIN (HBIG)

If HBIG is indicated (see appendix 8 re HBV PEP), it should be administered according to the manufacturer's guidelines. It should ideally be given within 48 hours of exposure but not later than 1 week after exposure.

Hepatect CP® (Biotest Pharm GmbH) 50 units/ml is the HBIG product available in Ireland.

The dose for post-exposure prophylaxis in adults is 500 units (10 ml). For children, the dose is 8 units (0.16 ml)/kg.

Hepatect CP® should be infused intravenously at an initial rate of 0.1 ml/kg/hour for 10 minutes. If tolerated, the rate of administration may gradually be increased to a maximum of 1 ml/kg/hour.

Do not dilute Hepatect CP® or mix Hepatect CP® with any fluid.

The first dose of HBV vaccine can be given on the same day as HBIG but at a different site.

Theoretical risk of infection

According to the Hepatect CP® Summary of Product Characteristics (SPC) (http://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/results/item?pano=PA0592/005/004&spcpara=6.0&t=HEPATECT%20CP):

"Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

The measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV. The measures taken may be of limited value against non-enveloped viruses such as HAV and parvovirus B19.

There is reassuring clinical experience regarding the lack of hepatitis A or parvovirus B19 transmission with immunoglobulins and it is also assumed that the antibody content makes an important contribution to the viral safety.

It is strongly recommended that every time that Hepatect CP® is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product."



MANAGEMENT OF ACUTE HEPATITIS C

Currently there is no recommended post-exposure prophylaxis for HCV. However, treatment of early infection has been shown to be successful.

A review of 17 published studies on therapy of acute hepatitis C was carried out by Alberti et al.¹ Almost all of these studies were small in size, uncontrolled and highly heterogeneous in respect of patient features, dose and duration of treatment, follow-up evaluation, and criteria used to define efficacy and safety. However, the authors concluded that the pooled results strongly support the benefit of interferon therapy in reducing chronicity of acute hepatitis C, a finding that was confirmed by a formal meta-analysis of several randomised controlled trials of acute hepatitis C treatment. The pooled data from 17 studies showed a sustained virological response (SVR) of 62% (range 37-100%) in the treated patients, compared with 12% (range 0-20%) in untreated individuals.

In the United Kingdom, the surveillance system for occupational exposures to BBVs in healthcare workers (HCWs)has reported that, of 10 HCWs who received treatment for acute HCV, all had achieved an SVR.²

In a review article on acute hepatitis C, Maheshwari et al state that, despite the absence of large randomised trials, it is reasonable to conclude that early treatment could reduce the chronicity of HCV infection.³ However, several issues of therapy are unresolved, such as: which patients to treat, when to start treatment and what regimen is optimal.

Recommendation:

- It is essential that patients who develop acute hepatitis C infection are diagnosed as soon as possible to allow for early treatment. Therefore, a HCV Ag or HCV RNA test on the recipient is carried out at six weeks and three months after the exposure incident.
- The recipient should also be counselled for symptoms suggestive of acute infection, e.g. fever, abdominal pain, vomiting, dark urine, yellow eyes.
- A person with symptoms suggestive of hepatitis, or a positive HCV RNA or Ag result, should be evaluated immediately by an appropriate specialist.
- The patient should be advised to avoid unprotected sexual contact.

References

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TETANUS

(Adapted from Royal College of Physicians of Ireland, National Immunisation Advisory Committee. Immunisation Guidelines for Ireland 2013. Chapter 21 - Tetanus (updated 25th August 2015). Available from: http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter21.pdf)

Prophylaxis for tetanus-prone wounds

The following wounds are considered tetanus-prone:

- Wounds contaminated with soil, faeces, saliva or foreign bodies
- Puncture wounds*, avulsions, burns or crush injuries
- Wounds or burns requiring surgical treatment which is delayed for more than 6 hours
- Compound fractures

Note: Occasionally, apparently trivial injuries can result in tetanus.

*Needlestick injuries in healthcare settings are unlikely to pose a risk of tetanus.

Risk assessment of wounds for use of vaccination and tetanus immunoglobulin (TIG)

Vaccination status	Clean wound	Tetan	us prone wound
Fully immunised (5 doses of tetanus vaccine at appropriate intervals)	Nil	Nil	Consider TIG*
Primary immunisation and age appropriate boosters complete	Nil	Nil	Consider TIG*
Primary immunisation or age appropriate boosters incomplete	Age appropriate tetanus vaccine and complete vaccine schedule	Age appropriate tetanus vaccine and complete vaccine schedule	TIG
Unimmunised or unknown vaccine status	Age appropriate tetanus vaccine and complete vaccine schedule	Age appropriate tetanus vaccine and complete vaccine schedule	TIG

^{*}Consider TIG for fully vaccinated patients who are immunocompromised

Important:

If both TIG plus a vaccine are to be given, administer at separate sites.

Refer to GP for follow-up vaccines.

Batch numbers and expiry dates must be recorded for all vaccines given.

This information MUST be communicated to the patient's GP so that:

- Duplication of vaccination does not occur
- Full records may be passed onto the relevant agencies in order that a full nationwide database is kept of batch numbers and expiry dates of vaccines given to children.

Specific anti-tetanus immunoglobulin

Indications

Prophylaxis with TIG is recommended for those with tetanus-prone wounds who:

• have not received at least 3 doses of tetanus toxoid and their last dose within 10 years (see table above)

or

• are immunocompromised, even if fully immunised (see Chapter 3 of Immunisation Guidelines for Ireland 2013).



Dose and route of administration

Prevention

250 units (1ml) intramuscularly into the anterolateral thigh.

The single dose of TIG is doubled to 500 units (2ml) when any of the following situations exist:

- The injury occurred more than 24 hours previously
- The patient weights more than 90kg
- The wound is heavily contaminated
- The wound is infected or involves a fracture



PRESCRIBING INFORMATION FOR EMERGENCY HORMONAL CONTRACEPTION (EC)

Please note that the provision of family planning services is not considered within the normal remit of the Emergency Department. However, there are situations where emergency hormonal contraception is considered appropriate.

When should emergency hormonal contraception be considered?

- In females presenting for post-exposure prophylaxis (or consideration of same) following potential sexual exposure to HIV.
- In females presenting for assessment following sexual assault.

Please note that insertion of a copper IUD is a more effective form of emergency contraception. Copper IUDs are available at Family Planning and Well Woman Clinics. Advice on how to obtain an IUD should be offered to all women attending for emergency contraception even if presenting within 72 hrs of unprotected sexual intercourse (UPSI).

1. Emergency Contraceptive Pill (ECP): Ulipristal Acetate (ellaOne®)

How does ulipristal acetate (UPA) prevent pregnancy?

UPA is a progesterone receptor modulator and the primary mechanism of action is thought to be inhibition or delay of ovulation. If administered immediately before ovulation UPA has been shown to suppress growth of lead follicles.^{2,3} There is evidence³ to suggest that UPA can prevent ovulation after the LH surge has started, delaying follicular rupture until up to 5 days later. Administration of UPA at the time of the LH peak or after has been shown to be ineffective in delaying follicular rupture.³

Although there have been studies that have shown an endometrial effect,^{4,5} the contribution of these endometrial changes to the efficacy of UPA (e.g. by inhibiting implantation) is as yet unknown.

There is currently a lack of evidence on the effect of UPA if inadvertently administered after implantation has occurred, but there have been no associated adverse outcomes in the small numbers of inadvertent pregnancies that have been reported to date.1

It is important to remember that women must not consider themselves protected against pregnancy for subsequent acts of intercourse. Therefore, after using emergency contraception, women should be advised to use a reliable barrier method until her next menstrual period.

When can ulipristal acetate (UPA) be given?

UPA should be given as soon as possible after UPSI. The efficacy of UPA has been demonstrated up to 120 hours after UPSI 1,6,7 and there is no apparent decline in efficacy within that time period.6

No data are available on the efficacy of ellaOne when taken more than 120 hours (5 days) after unprotected intercourse.

What is the dose?

A single dose of UPA 30mg tablet is given orally.1

If vomiting occurs within 3 hours of ellaOne intake, another tablet should be taken.¹

The SPC (summary of product characteristics) states that concomitant use of ellaOne with CYP3A4 inducers is not recommended due to interaction (e.g. rifampicin, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoine, nevirapine, oxcarbazepine, primidone, rifabutine, St John's wort/Hypericum perforatum, long term use of ritonavir). 1

The FSRH Guidelines (2011) do not currently support doubling the dose of UPA when using drugs that may reduce UPA's efficacy.8

Contraindications to using ulipristal acetate (UPA)

Although there has been limited inclusion of under-18s in clinical trials of UPA, age is not listed as a contraindication within the SPC.1



- The SPC states that contraindications to use include a hypersensitivity to UPA or any of the other components, and also pregnancy.1
- 2) Use is not recommended in women with severe asthma insufficiently controlled by oral glucocorticoids.
- In addition the SPC advises caution in women with hepatic dysfunction, hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.1
- 4) The SPC states that after intake of UPA, breastfeeding is not recommended for up to 36 hours.¹

Ulipristal Acetate (ellaOne®) emergency contraception is available, over the counter, without prescription to women over 16 years of age.

Please refer to the Faculty of Sexual and Reproductive Healthcare website http://www.fsrh.org/searchresults.asp?q=ellaone) or the Summary of Product Characteristics (http://www.medicines.ie/medicine/15370/SPC/ellaOne+30+mg/) for further information.

2. Emergency Contraceptive Pill (ECP): Levonorgestrel (NorLevo® or Prevenelle®) How does levonorgestrel prevent pregnancy?

The exact mode of action of levonorgestrel in preventing pregnancy following UPSI is not known. If taken in the preovulatory phase it will usually inhibit ovulation for 5-7 days, by which time any sperm in the upper reproductive tract have lost their fertilising ability. It may also cause endometrial changes that discourage implantation.

It is important to remember that women must not consider themselves protected against pregnancy for the rest of their cycle following a dose of levonorgestrel. This is particularly important if levonorgestrel has the effect of delaying ovulation.

Results from a recent clinical study 9 showed that a 1500 microgram single dose of levonorgestrel (taken within 72 hours of UPSI) prevented 82% of expected pregnancies.

When can levonorgestrel be given?

Levonorgestrel should be given as soon as possible after UPSI. It is most effective when given within 72 hours of UPSI. Efficacy is reduced after this time. 10, 11

Use of levonorgestrel between 73 and 120 hours post UPSI may be associated with a reduced expected pregnancy rate and may be considered. Use of levonorgestrel after 72 hours is outside of the product licence. Women in these circumstance should be offered ellaOne or advised to attend a family planning or well woman clinic for insertion of a copper IUD.

What is the dose?

The usual dose of levonorgestrel is 1.5mg stat, given as soon as possible after UPSI. 10, 11

It is not necessary to give prophylactic antiemetics routinely with levonorgestrel. Antiemetics can be reserved for women who give a history of vomiting when they have taken levonorgestrel in the past or where a woman is receiving a second dose because of vomiting within 3 hours of taking levonorgestrel.

The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers. Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel containing medication include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin. 10, 11

Medicines containing levonorgestrel may increase the risk of cyclosporin toxicity due to possible inhibition of cyclosporin metabolism. Tor further information on drug interactions check with a pharmacist or consult the British National Formulary, BNF.

In women taking liver enzyme inducers the current recommendation from the Faculty of Family Planning is that the women take 3mg levonorgestrel stat. 12 They should also be informed of the option of being referred to a family planning clinic for insertion of an IUD.

Contraindications to using levonorgestrel

- There is no age limit to the use of levonorgestrel, although there is little data on its use in females under 16 years of age.
- The WHO Medical Eligibility Criteria for Contraceptive Use advises that there are no medical contraindications to levonorgestrel.¹³



- 3) The SPC (summary of product characteristics) for Prevenelle and NorLevo state that levonorgestrel is not recommended in patients with severe hepatic dysfunction. 10, 11
- Prevenelle and NorLevo contain lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. 10, 11
- 5) Women with severe malabsorption syndromes (such as Crohn's disease) may experience a reduction in efficacy of oral emergency contraception.¹¹
- 6) Any women known to have hypersensitivity to levonogestrel or any of the other components of the tablet should use levonorgestrel with caution.

For further information on the Summary of Product Characteristics see: http://www.medicines.ie/medicine/11933/SPC/Norlevo+1.5mg+tablet/ or http://www.medicines.ie/medicine/16228/SPC/Prevenelle+1500+microgram+Tablet/

Levonorgestrel emergency contraception is available, over the counter, without prescription to women over 16 years of age.

(Adapted from Faculty of Sexual & Reproductive Healthcare Clinical Guidance on Emergency Contraception, August 2011, updated January 2012.14)

Time Frames for Emergency Contraception			
METHOD	TIME FRAME		
Ulipristal acetate 30mg (one tablet) orally	As soon as possible but within 5 days (120 hours) of unprotected intercourse or expected date of ovulation. ^{15, 16}		
Single dose of Levonorgestrel 1.5 mg. (one tablet) orally.	As soon as possible within 72 hours. 10, 11, 17 Some evidence it is of value up to 5 days (120hrs) but the efficacy is uncertain and it is not licensed for use after 72 hours. 17, 18, 19		
A copper containing intra-uterine device *	After 72 hours but within 5 days (120 hours) of unprotected intercourse or expected date of ovulation. ^{20, 21, 22}		

^{*}Available from some family planning and well woman clinics

Source: HSE Recent Rape/Sexual Assault: National Guidelines on Referral and Forensic Clinical Examination in Ireland. 3rd edition; 2014.23

For patient information leaflet on emergency contraception, see appendix 32.



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OCCUPATIONAL BLOOD OR BODY FLUID **EXPOSURE**

This section relates to workplaces where a risk assessment has indicated that blood and body fluid exposures are an occupational hazard. Such occupations include, but are not limited to, the healthcare sector, members of An Garda Siochana, and prison personnel.

Each occupational health service should have a local policy for the prevention and management of blood and body fluid exposures. This policy should take into account local expertise and local resources, which in turn will dictate whether the employee is managed at the initial stage in the occupational health department (OHD), local emergency department (ED) or elsewhere.

In occupations where infectious exposures are recognized as potential hazards, a hierarchical approach to management is required and the focus should be on prevention.¹

Employees should be informed of the correct course of action to follow in the event of an occupational blood or body fluid exposure at commencement of their employment. Furthermore, employees should be reminded that they should not manage these exposures themselves but should report the exposure and follow local management arrangements.

Training of employees in the correct use of instruments (including personal protective equipment) is recommended.^{2, 3, 4} While this should reduce the frequency of exposures, unfortunately it will not completely eliminate blood and body fluid exposures. Where vaccination is available, it must be provided by the employer. At present, this is only available for hepatitis B (see appendix 11, Hepatitis B vaccine). Where an employee does not achieve an adequate protective antibody response, they should be counselled regarding the risk of exposures to hepatitis B infected blood and the recommended management of such exposures. This should be documented.

The needlestick/sharps exposure algorithm (appendix 3) outlines the initial management of any employee who is exposed to blood or body fluids in the course of their work. Further details and relevant background information are included elsewhere in the guideline. Local resources will dictate where the worker is managed at the initial stage i.e OHD, ED or other and where follow-up is carried out i.e. OHD, infectious diseases service.

In addition to the risk of disease transmission, blood and body fluid exposures are a recognised cause of distress among recipients, with potential medical and legal ramifications. Anxiety, insomnia and depression are frequently reported, while more extreme cases of post-traumatic stress disorder and panic attacks have also been described. To minimise this, clear and consistent information should be provided including the risks of disease transmission, details of the management and follow-up plan, symptoms suggestive of seroconversion illness, likely side effects and potential drug interactions of treatment (where relevant) and any workplace/life-style modification that may be indicated (see information leaflets, appendices 28 and 31).

In all cases, the details of the injury, including the context of the injury and the nature of the device involved, should be recorded (appendix 1, patient management form). This information is required both in the initial assessment process (see Section 2 of the Guidelines) and to inform future decision making (e.g. purchasing policies, training, counselling requirements) regarding preventative measures. In addition, the OHD should be able to provide anonymous details of injuries to the Health & Safety Authority and for auditing purposes.

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HUMAN BITE INJURIES, SALIVA AND TRANSMISSION OF BLOODBORNE VIRUSES

Summary of BBV transmission risk from exposure to saliva

The risk of BBV transmission from exposure to saliva is very low overall. It is related to the type of injury, the type of virus present, and the amount of blood in the saliva. Saliva cannot transmit BBVs unless blood is present, although blood can be present without being visible. The risk is increased if there is visible blood, poor oral hygiene, or if the source or recipient is immunocompromised. If there is a large amount of blood present in the saliva, the risk is similar to the risk from exposure to blood.

With bite cases, an individual risk assessment is required, taking account of the extent of the injury, the HBV immunisation status of the injured person and the BBV status of the source and the injured person. With the exception of a deep bite wound sustained from a HBV infected, or high-risk, source, in a recipient who is not HBV immune, the risk of BBV transmission is negligible. The evidence suggests that the risk of transmission from a HIV positive or HCV positive source is minimal to non-existent. A recipient of a bite that breaches the skin but with no visible source blood does not require any follow-up from the point of view of HIV and HCV.

HBV vaccination should be advised for an unvaccinated recipient following a percutaneous or mucous membrane exposure to saliva from a source who is HBV infected or high-risk but of unknown sero-status (see appendix 8). HBIG may also be indicated, depending on the risk assessment, but generally only if the source is HBV positive. If HBIG is required, it should ideally be given within 48 hours of exposure, but not later than a week after exposure. HIV PEP would not be indicated except in extreme circumstances.

Saliva and bloodborne viruses

Although composed mainly of water (99%), saliva is a complex secretion. Saliva can be considered as gland-specific saliva or whole saliva. Whole saliva (mixed saliva) is a mixture of oral fluids and includes secretions from both the major and minor salivary glands, in addition to several constituents of non-salivary origin, such as gingival crevicular fluid, expectorated bronchial and nasal secretions, serum and blood derivatives from oral wounds, bacteria and bacterial products, viruses and fungi, desquamated epithelial cells, other cellular components, and food debris. Saliva has protective properties and contains a variety of antimicrobial constituents and growth factors.

In general, complete bloodborne viruses are not secreted into saliva, even though the bloodborne viruses HBV, HCV and HIV have all been detected by molecular techniques in saliva of infected patients. BBVs get there from blood leakage into the oral cavity, either from soft or hard tissue trauma or from periodontal bleeding. Salivary fluids exiting the glands mirror the composition of macromolecules in blood. Viral particles usually are too large to filter through the salivary glands and into saliva. However, individual components of unassembled viral particles can get through the glands, such as hepatitis B surface antigen or DNA, and appear in saliva without the presence of blood. However, transmission can only occur if completely assembled HBV particles are in the saliva. No studies are available that prove that HBV is transmitted through saliva in the absence of blood. The same holds true for HCV and HIV. **The bottom line is that saliva can only transmit BBVs to the extent that blood is present.**

However, even when blood is not visible, it can still be present in limited quantities in the saliva and therefore saliva is considered a potentially infectious material in any percutaneous or mucous membrane exposure by the US CDC and Occupational Safety and Health Administration



(OSHA). A bite from someone known to have poor gum health, diabetes, immunocompromise, or on anticoagulant medication, may increase the risk. Dentists are occupationally exposed to saliva, and prior to 1982 when the HBV vaccine was not available and exam gloves were not routinely used, their seroprevalence of HBV markers of infection was about 15%. The HCV seroprevalence in dentists is about 0.5%, and for HIV it is under 0.025%. Therefore, the risk of transmission from percutaneous or mucous membrane contact is proportional to the amount of blood in the saliva and the type of virus present.

Hepatitis B

HBV has been demonstrated in the saliva of HBV infected people and a high correlation has been shown between HBV DNA levels in serum and saliva. 1,2,3 Saliva has been suggested as a vehicle for horizontal transmission of HBV among children. A study of paired saliva and plasma samples from 43 children with chronic HBV infection found high levels of HBV DNA (mean 33.9 x 103 IU/ml) in saliva of HBeAg positive children but HBV DNA was not detectable in the saliva samples from the HBeAg negative children. 4

Transmission of HBV by human bite has been described and definitively proven by genome sequencing of the virus in the carrier and in the bitten person.⁵

Hepatitis C

HCV has been shown to be frequently present in the saliva of HCV infected people.^{6,7,8} However, epidemiological studies show that infection by contact with contaminated saliva is rare.⁸ It may be that the specific and non-specific defence mechanisms present in saliva could attenuate or abolish the infective capacity of viral particles. Saliva of patients with chronic HCV infection contains specific IgG and IgA neutralising antibodies directed against the E1 and E2 surface glycoproteins which could block viral adhesion to the host cell.⁹ There is conflicting evidence about the relationship between the presence of the hepatitis C virus in the saliva and the viral load in the blood, with one review suggesting a direct relationship⁸; however, one study found that the presence of HCV in saliva is independent of the level of viral load.¹⁰

There have been no reports proving the direct transmission of HCV by saliva: the possibility of transmission of HCV by a human bite has not been confirmed by molecular studies. Data suggest that nosocomial transmission of HCV to dental HCWs is unlikely. A review of the evidence on HCV transmission by saliva found that the prevalence of HCV infection among dental health care workers exposed to saliva is similar to that for the general population.

HIV

Salivary proteins play a role in the inactivation of HIV and preventing its infectivity. HIV virus is detectable in saliva, especially in immune compromised patients as CD4 count declines and plasma viral load increases. In countries where HIV positive patients receive successful anti-viral therapy (HAART), viral load is undetectable in most cases and the risk of oral transmission of HIV is probably low to non-existent.

Bite injuries represent a potential means of transmitting HIV. However, HIV transmission by this route has been reported rarely.¹³ The few documented cases of possible HIV transmission following bites were in adults exposed to blood-tinged saliva.¹⁴

Transmission might theoretically occur either through biting or receiving a bite from a HIV-infected person. Biting a HIV-infected person, resulting in a break in the skin, exposes the oral mucous membranes to infected blood; being bitten by a HIV-infected person exposes non-intact skin to saliva. Saliva that is not contaminated with blood contains HIV in much lower titres and constitutes a negligible risk. A bite is not considered a risk exposure to either party when the integrity of the skin is not disrupted.



A review of literature on human bites and HIV transmission¹⁵ concluded that it is possible for a bite from a HIV-infected individual to transmit HIV. The likely risk of transmission is increased if:

- · Blood is present in the oral cavity
- The bite breaks the skin
- The bite is associated with a previous injury
- The biter is IgA deficient.

HUMAN BITE INJURIES

(appendix 6, algorithm for management of human bites)

Background

Human bite wounds may result in infection such as cellulitis, osteomyelitis or septic arthritis. Current data suggest an infection rate from human bite wounds of the order of 10% to 50%, depending on the wound type and location. However, human bite wounds to the hand are associated with infection rates of almost 50%. A clenched-fist injury ("fight bite") is considered the most serious of all human-bite wounds, with bites to feet, face, or skin overlying cartilaginous structures, or bites that penetrate deeper than the epidermal layer also significant. Human bites in other areas pose no greater risk than animal bites.

Human bites cause more serious infections than dog and cat bites because the human oral flora contains multiple species of bacteria. Human bite wound pathogens include aerobic bacteria (such as *Streptococci*, *S aureus* and *Eikenella corrodens*) and anaerobic bacteria (such as *Fusobacterium*, *Peptostreptococcus*, *Prevotella*, and *Porphyomonas spp*. ¹⁶

Because individuals with human bite wounds have a **high-risk of serious bacterial infections** close assessment of any bite wound is necessary. Overall, the **risk of transmission of bloodborne viruses** by human bites is likely to be low (see above). However, a significant risk of transmission must be considered following a human bite from a high-risk individual where a breach of the skin occurs and particularly if there is blood in the saliva. The risk is highest where the biter is HBV positive.

Pathophysiology

In a closed-fist injury ("fight bite"), forces sufficient to break the skin from striking an opponent's tooth often inoculate the extensor tendon and its sheath. As the hand is flexed at the time of impact, the bacterial load is transferred caudally when the hand is opened and the tendon slides back to its relaxed state. Resulting contamination cannot be removed readily through normal cleansing and irrigation.

When a finger is bitten, such as in a chomping-type injury, tendons and their overlying sheaths are in close proximity to the skin. The wound may appear to be a minor abrasion-type injury, but careful inspection is required to rule out deep injury.

When a tooth strikes the head, even a deep puncture wound may appear innocuous. Deep, subgaleal, bacterial contamination is possible. This is especially true in young children who have relatively thin soft scalp and forehead tissue.

Frequency, age and sex

In a 4-year retrospective review in the United Kingdom, 421 (13%) human bites were identified out of 3136 case notes in emergency medicine departments. The majority of those bitten were young males, with 44% of the males aged 16-25 years. The male-to-female ratio was 3:1. Closed-fist injuries are encountered almost exclusively in young males. Toddlers frequently bite one another, but injuries usually are superficial and low-risk.

Mortality/Morbidity

The primary concern with human bites of the hand is infection, which can be severe because of spread along tendon sheaths and deep into the hand. Surgical incision and drainage may be needed. Resultant scarring and tissue damage may compromise normal function of the hand.



Infection is also the major complication of bites in other areas of the body. Most can be treated adequately; however, infections of poorly vascularized structures, such as ear cartilage, may be difficult to treat.

Other serious infectious complications such as deep soft tissue infection, septic arthritis, osteomyelitis, infectious tenosynovitis, bacteraemia, necrotizing fasciitis, and osteomyelitis of the skull vault have been associated with human bites.

Risk assessment following a human bite^{17, 18}

History

- · Circumstances of the injury
- · Time of injury (after three hours, the bacterial count in a wound increases dramatically)
- · Past medical history, including immunocompromised state
- · Tetanus immunisation status
- · Routine or recent medications (especially steroids, anticoagulants)

Examination

- · Vital signs: Temperature, blood-pressure and heart rate.
- · Dimensions of wound, including depth
- · Assess for signs of infection, drainage or tissue loss
- · Assess for vascular, neurological or tendon injury
- · Photographic documentation (patient's consent is required)

Special tests – to be considered

- · Labs: wound swab, blood culture and sensitivities, complete blood cell count with differential, HIV, HBV, HCV serological status.
- · Cultures for both aerobic and anaerobic bacteria are recommended if the wound shows clinical evidence of infection.
- · Radiographic: for wounds near a joint or bone to evaluate for foreign bodies (e.g. tooth fragments).

Treatment of human bite wounds

Wound management plays a key role in prevention of infection. The surface should be cleaned and lacerations should be irrigated with sterile saline using pressure irrigation. Devitalized tissue should be debrided. The management of puncture wounds is more controversial. High pressure irrigation into a puncture wound should be avoided.

Clinical findings which indicate infection of bite wounds include erythema, swelling, tenderness, purulent drainage, lymphangitis and fever. Wounds which are infected at presentation should be swabbed and cultured, and blood cultures should also be taken. Infectious diseases/clinical microbiology advice should be sought regarding appropriate antimicrobial treatment, and surgical opinion should be sought regarding debridement and other surgical interventions. Inpatient treatment with intravenous antibiotics and surgical input is often required.

The use of prophylactic antibiotics after human bites to the hand has been shown to reduce the risk of infection.²⁰ Prophylactic antibiotics should be given for human bites if *any* of the following are present:

- bite to hand (clenched fist injuries are particularly high-risk), foot, face or ear;
- bite through dermis or puncture wound;
- moderate-severe wound with crush injury;
- wound near bone or joint;
- wounds requiring closure;
- wounds in areas of impaired venous/lymphatic drainage including post-mastectomy;
- immunocompromised hosts (including patients with transplants, HIV, post-splenectomy, cirrhosis or diabetes mellitus).



The recommended regimen for prophylaxis of infection is co-amoxiclav 625 mg tds for 3 to 5 days, with alternatives for penicillin allergic patients including doxycycline 100 mg bd plus metronidazole 400 mg po tds, or ciprofloxacin 500 to 750 mg bd plus metronidazole.¹⁹

HBV vaccination should be advised for all unvaccinated recipients of a human bite wound. HBIG may also be indicated, depending on the risk assessment, but generally only if the source is HBV positive (see appendix 8).

HIV PEP would almost never be indicated following a human bite except in extreme circumstances.

Tetanus prophylaxis may be indicated (see appendix 15).

Outpatient follow-up of patients with human bites is advised to monitor for any evidence of development of infection.

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COMMUNITY ACQUIRED NEEDLESTICK INJURIES

Community acquired needlestick injuries (CANSIs) have not been well described, and the evidence base on which to recommend management strategies is poor. CANSIs cover a wide spectrum from criminal assault with blood filled syringes to children playing with discarded syringes in public parks.

Although community needlestick injuries are a common source of anxiety for the public and for the health care providers who treat them, transmission of BBVs in a non-clinical setting is exceedingly rare.² CANSI due to deliberate assault with a blood filled syringe represents a higher risk than average.¹

In contrast to the situation with needlestick injuries in health care workers, the source of blood in discarded needles is usually unknown, injury does not occur immediately after needle use, the needle rarely contains fresh blood, any virus present has been exposed to drying and environmental temperatures, and injuries are usually superficial.³

The risk of BBV transmission through a needlestick injury from a discarded needle/syringe is likely to depend on several factors. These factors include the prevalence of BBVs among PWID in the particular setting, the type of injury sustained, the viability of the particular virus outside the body, how recently the needle/syringe has been used, the level of immunity (in the case of HBV) and the availability and use of PEP (in the case of HBV and HIV).⁴

Reported cases of BBV transmission following a CANSI

There are currently few reported incidents of BBV infections thought to be secondary to a CANSI. A case of presumed acute HBV infection was reported in a 4 year old boy in Spain who did not receive post-exposure HBV vaccine or HBIG.⁵ In 2011, a case of acute HBV infection occurring 2 months after a CANSI was reported from Australia. The patient had a history of incomplete vaccination and HBV vaccine booster was delayed. He did not receive HBIG.² Three cases of HCV seroconversion in adults following needlestick injuries in the community have been reported.^{6,7} No HIV infections have been reported after a CANSI.⁸

Case series

In a study in an emergency medicine department in Sydney, 124 cases of CANSI were identified over a 6 year period, of which 120 were described. The median age was 26 years. There was a marked male predominance. Injuries were work-related in 36% of cases, predominantly police officers and cleaners. 68% of cases were as a result of exposure to discarded syringes. The source of the blood in the syringe was identifiable in only 12% cases. 54% of patients received HBV PEP and 8% received HIV PEP. At 6 months post-injury there were no HBV, HCV or HIV seroconversions in the 10 patients for whom there was follow-up serology.¹

A large study in Montreal of 274 paediatric patients presenting with CANSI between 1988 and 2006 found no seroconversions. Of patients who were not known to be immune to HBV, 82.2% received HBIG and 92.6% received HBV vaccine. HIV chemoprophylaxis was given to 39% of patients who presented after 1997. The most common site of injury was the hand. Most of the injuries were superficial and blood was rarely visible on the needle or syringe.

Several other studies reported the outcome of CANSIs in children presenting to emergency departments in Edinburgh, Dublin, Melbourne and Birmingham. No cases of seroconversion for BBVs were detected. However, compliance with follow-up was generally poor.^{9, 10, 11, 12}

A review of the literature up until September 2007 by the Canadian Paediatric Society yielded 12 case series from areas of high prevalence of bloodborne viruses. These involved a total of 483 children with follow-up for HIV, 452 for HBV and 265 for HCV. There were no infections. The majority of children received HBV prophylaxis, if it was indicated. 130 children received antiretroviral prophylaxis.³



Viability of BBVs in the environment

CANSIs are likely to carry a considerably smaller risk of BBV transmission than injuries in the occupational setting as needles found in the community have been exposed to environmental temperatures and drying for an indeterminate period of time.⁸

Environmental HBV transmission is well documented and relates to its high concentration in blood and its ability to maintain infectivity on environmental surfaces.⁴ HBV has been demonstrated to survive in dried blood at room temperature on environmental surfaces for at least 1 week.¹ HBV has been detected in discarded needles.³

HCV is thought to be a fragile virus which would be unlikely to survive in the environment, but there are little data at this time.³ Support for the potential for environmental HCV transmission comes from studies that demonstrate high levels of HCV transmission in health care settings – particularly renal dialysis units and wards with immunocompromised patients.⁴

HIV is a relatively fragile virus and is susceptible to drying. However, survival of HIV for up to 42 days in syringes inoculated with the virus has been demonstrated, with duration of survival dependent on ambient temperature. One study found no traces of HIV proviral DNA in syringes discarded by intravenous drug users, while another study found HIV DNA in visibly contaminated needles and syringes from shooting galleries.³ However, the presence of viral DNA is not a direct demonstration of viable virus.

Risk of BBV transmission

The risk of transmission of BBVs following CANSIs is difficult to estimate. HBV represents the highest risk. The likelihood of transmission of HCV or HIV is very remote.

The risk of BBV transmission following needlestick injuries in the occupational setting has been estimated and may be of value in estimating the risk in CANSIs:

The risk of acquiring HBV from an occupational needlestick injury when the source is hepatitis B surface antigen (HBsAg) positive ranges from 2% to 40%, depending on the source's level of viremia.³

The average incidence of anti-HCV seroconversion after accidental percutaneous exposure from a HCV positive source is 1.8%.¹

The risk of acquisition of HIV from a hollow-bore needle with blood from a known HIV seropositive source is between 0.2% and 0.5%, based on prospective studies of occupational needlestick injuries. The risk is increased with higher viral inoculum, which is related to the amount of blood introduced and the concentration of virus in that blood. The size of the needle, the depth of penetration and whether blood was injected are also important considerations. In most reported instances involving transmission of HIV, the needlestick injury occurred within seconds or minutes after the needle was withdrawn from the source patient.³

Management of CANSI (see appendix 3, algorithm for needlestick exposure) *Risk assessment*

Although the actual risk of infection from such an injury is very low, the perception of risk by patients results in much anxiety. Evaluation and counselling are needed.

Individualised risk assessment is essential for every case of CANSI as the source is rarely identified. However, if the source can be identified, then all attempts should be made to assess their risk factors and to test them for BBVs (see section 3.3 Investigation of source).

Post-exposure prophylaxis

HBV: HBV vaccine with an accelerated schedule should be offered to non- and partially-immune recipients. HBIG may occasionally be indicated (see HBV PEP appendix 8).

HCV: There is no effective post-exposure prophylaxis for HCV. However, treatment of early infection has been shown to be effective. Baseline and follow-up testing at 6 weeks and 3 months for HCV



would therefore enable early therapeutic intervention following HCV transmission⁴ (see appendix 14 Treatment of acute hepatitis C).

HIV: HIV PEP remains an unresolved issue. No studies have directly measured the effectiveness of PEP in decreasing the risk of HIV transmission in non-occupational settings. ¹² The risk of HIV transmission, and risks and benefits of antiretroviral prophylaxis should be assessed on a case-by-case basis, and guided by expert opinion. ¹ Antiretroviral prophylaxis should be recommended only in cases of high-risk. ^{3, 8, 12} (See appendix 7, HIV PEP)

The factors associated with increased risk are:

- the source is considered likely to have HIV
- the injury was deep, penetrating
- the needle was large-bore, hollow lumen
- the incident involved a needle with visible blood (particularly fresh blood)
- blood may have been injected.

BBV testing and follow-up

Follow-up after any significant needlestick injury is essential. The clinician dealing with the initial incident should ensure that the patient understands the importance of follow-up, and that appropriate arrangements are made. Patients sometimes assume that if blood tests that are performed at the time of injury are negative, then there is no possibility of infection and no need for further testing.³ If a significant exposure has occurred, testing the recipient for BBVs should be carried out at baseline, 6 weeks and 3 months (see appendix 9 Testing of recipient).

Testing of needles and syringes

Testing needles and syringes for viruses is not indicated. Results are likely to be negative, but a negative result does not rule out the possibility of infection.³

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Injury in Dental Practice or Primary Care Medical Practice Form to be given to the recipient's treating doctor



On-site assessment form for incidents such as needlesticks and human bites where there is a risk of bloodborne virus (BBV) transmission	
Reporting time: Dentist name: Responsible person:	Reporting date: Dentist signature: Contact phone number: After hours number:
SOURCE DETAILS Is the source known? Has the source been informed of incident? Has the source consented to medical history being passed on? Has the source consented to testing? Yes No Has the source consented to testing?	Signed: Responsible Person If consent to testing given: Source first name:
If consent given, is there a relevant med history? Yes No if yes - details? Yes No	Source mobile phone no.:
RECIPIENT DETAILS Name Address Gender M F Date of birth Telephone number Mobile Occupation Work address	Medical History (incl. immunosuppression) Specify if recipient known to be positive for HBV, HCV or HIV Medications Allergies if female Pregnant Breastfeeding Hepatitis B Vaccination 1 dose 2 doses Full course Year Antibody result if known Tetanus Date of last vaccination Number of doses
ASSESSMENT OF EXPOSURE RISK Brief description of injury including date, time and place of injury	Nature of injury Needlestick
Nature of material e.g. blood, saliva	Severity of needlestick or sharp injury Superficial - surface scratch, no blood appeared Moderate - penetrated skin and blood appeared Deep - puncture, with or without blood appearance
if NOT blood, was fluid blood stained Yes No Other injury Describe	Human bite Skin breached Splash Non-intact skin Mucous membrane Splash Eye
HEALTHCARE EXPOSURES Area where exposure occured Was this an 'exposure prone procedure'? Yes No Were gloves worn at the time of the injury? Yes No	Instrument (if any) which caused the injury What was the instrument originally intended for? Did the instrument have a safety mechanism? Yes No Was the safety mechanism activated? Yes No



Hepatitis B virus: epidemiology and transmission risks

Hepatitis B virus (HBV) infection is a serious and common infectious disease of the liver, affecting millions of people throughout the world. The incubation period for HBV is 45-180 days, most commonly 60-90 days.¹

Clinical information

Acute infection is clinically recognised in only a small proportion of cases; less that 10% of children and 30-50% of adults show icteric disease. In those with clinical illness, the onset is usually insidious, with anorexia, vague abdominal discomfort, nausea and vomiting, sometimes arthralgia and rash, often progressing to jaundice. Following acute HBV infection, the risk of developing chronic infection varies inversely with age. Chronic HBV infection occurs among about 90% of infants infected at birth, 25-50% of children infected at 1-5 years of age and about 1-10% of persons infected as older children and adults. An estimated 15-25% of persons with chronic HBV infection will die prematurely of either cirrhosis or hepatocellular carcinoma.¹

Vaccination

HBV can be effectively prevented by vaccination. A safe and effective vaccine has been available since the 1980s. The complete vaccine series induces protective antibody levels in more than 95% of infants, children and young adults. After age 40, protection following the primary vaccination series drops below 90%. Protection lasts at least 20 years and should be lifelong.² Since 2008, hepatitis B vaccine has been included in the childhood immunisation programme in Ireland, alongside the targeted immunisation programme for those individuals who are at increased risk of HBV because of their occupation, lifestyle or other factors. These include healthcare workers (HCW), prison and security personnel, contacts of cases, people who inject drugs, people with certain medical conditions, clients in learning disability centres, people with multiple sexual partners, men who have sex with men, prisoners, and travellers to and immigrants from HBV endemic areas.³

Transmission

HBV has been found in virtually all body secretions and excretions. However, only blood, body fluids containing visible blood, semen and vaginal secretions represent a risk of transmission.⁴ HBV is transmitted by percutaneous and mucosal exposure to infective blood or body fluids. Major modes of HBV transmission include sexual or close household contact with an infected person, perinatal mother to infant transmission, injecting drug use and nosocomial exposure.¹

Percutaneous exposures that have resulted in HBV transmission include transfusion of unscreened blood or blood products, sharing unsterilised injection needles for IV drug use, haemodialysis, acupuncture, tattooing and injuries from contaminated sharp instruments sustained by hospital personnel.⁵

HBV is stable on environmental surfaces for at least 7 days and is 100 times more infectious than HIV.

Serological markers for HBV

HBsAg: Hepatitis B surface antigen is a marker of infectivity. Its presence indicates either acute or chronic infection.

HBeAg: Hepatitis B e antigen is a marker of a high degree of infectivity and correlates with a high level of HBV replication.

Anti-HBs: Antibody to hepatitis B surface antigen is a marker of immunity, either an immune response to HBV infection or to vaccination.

Anti-HBc: Antibody to hepatitis B core antigen is a marker of HBV infection.

Prevalence of HBV infection in Ireland, Europe and the world

Ireland

The prevalence of HBV in the general population in Ireland is low. However, HBV is more prevalent in certain sub-groups of the population.⁶ The prevalence of HBV is higher in injecting drug users, people born in countries of intermediate (2-7%) or high (>8%) hepatitis B endemicity, MSM, people with multiple sexual partners, household or sexual contracts of known cases.⁷

The prevalence of HBV infection is generally lowest in the blood donor population, followed by the general population, then pregnant women, then high-risk groups. To determine the risk of HBV in migrant populations, it is necessary to look at data on their country of origin.

The World Health Organization has classified Ireland as a country of low prevalence for HBV, i.e. prevalence of HBsAg <2%. The European Centre for Disease Prevention and Control (ECDC) carried out a literature review in 2010 of publications dated 2000-2009 on the prevalence of viral hepatitis in Europe. It reported that the HBsAg prevalence in the general population in Ireland is estimated to be 0.1%. Ireland and the Netherlands have the lowest prevalence of HBV infection in Europe. It also reported that the HBsAg prevalence rates in blood donors and pregnant women in Ireland are among the lowest rates in Europe.



Low risk populations in Ireland

General population

A European HBV seroprevalence study using residual sera showed a low prevalence in Irish samples collected in 2003 (anti-HBc 1.7%, HBsAg 0.1%). A national study of oral fluid samples collected by postal survey in 1998-1999 estimated anti-HBc prevalence in Ireland to be 0.51%.

Blood donors

Of 313,019 first time blood donors tested by the IBTS between 1997 and 2015, 34 (0.011%) were found to be HBsAg positive. (Personal communication, Dr Joan O'Riordan, IBTS, July 2016).

Pregnant women

Routine antenatal testing for HBsAg was introduced in the Rotunda Hospital in 1998. Uptake was almost 100% and >16,000 pregnancies were screened between January 1998 and June 2000. This showed a HBsAg prevalence of 4.2% in non-EU women and 0.03% in Irish women tested. Screening of >24,000 pregnant women in the West of Ireland in 2004-2009 demonstrated a prevalence of HBsAg of 0.21%, and all positive women were thought to be of non-Irish origin.

High risk populations in Ireland

Prisoners

A national cross sectional survey of Irish prisoners in 1998 showed a prevalence of anti-HBc of 8.7% total, and of 18.5% in prisoners who were people who inject drugs.¹³

People who inject drugs

A cross-sectional study of 316 opiate users attending 21 addiction treatment centres in the HSE East was carried out between Dec 2001 and Jan 2002. The prevalence of HBsAg was 2% and of anti-HBc was 17%.¹⁴

Homeless people

Homeless people also have evidence of increased exposure to HBV, with a prevalence of anti-HBc of 9% in a study performed in Dublin in 1999-2000.³

Asylum seekers

Screening of asylum seekers in the HSE eastern region 1999-2003 found a prevalence of HBsAg of 5%. 15

Trends in hepatitis B infection in Ireland

Hepatitis B is a notifiable disease in Ireland. There was a dramatic increase in annual HBV notifications between 1997 (31 cases) and 2008 (919 cases), mostly attributable to large numbers of people immigrating to Ireland from HBV endemic countries. Between 2000 and 2010, 95% of asylum applicants, and 73% of new work permit recipients, were from countries with intermediate or high HBV endemicity. The number of hepatitis B cases reported in Ireland increased by 5% in 2014 with 445 cases (9.7/100,000) compared with 425 cases in 2013. However, there has been a general downward trend in the number of reported cases since peak levels in 2008 (n=901). The trend (a decline since the peak in 2008 with an increase in 2014) correspond to immigration trends in Ireland during the same period. 16

Between 2010 and 2014, 8% of reported cases of hepatitis B were acute and 92% were chronic. The majority of acute cases of hepatitis B were sexually acquired. Where reported, the risk factors for chronic infection included, born in an endemic country (69%), sexually acquired (13%) and vertical transmission (5%).¹⁶

Hepatitis B infection in Europe

Although there is a decreasing trend in HBV, each year there are between 7,000 and 8,000 newly diagnosed cases of HBV in the EU/EEA region.¹⁷ There has been a steady downward trend in the reported rates of acute cases in Europe that is likely related to the impact of vaccination campaigns.¹⁸ 99% of countries have integrated HBV into routine immunisation (2014).¹⁹ The total percentage of people infected with HBV varies between different countries, with higher rates in the southern part of Europe. The country with the highest prevalence (>4%) is Romania followed by medium prevalence countries (>1-2%), Spain, (parts of) Italy, and Greece. Countries with a low prevalence (<1%) include Belgium, the Czech Republic, Finland, Germany, Ireland, Netherlands, Slovakia and Sweden.¹⁷

The most severely affected population groups are people who inject drugs, sex workers, men who have sex with men, people living with HIV, inmates, and immigrants from high-endemic regions. In some countries, sexual transmission is more common than transmission through household contacts or injecting drug use.¹⁷

In 2013, 19,101 cases of hepatitis B infections were reported in 28 EU/EEA member states, a crude rate of 4.4 / 100,000 population. ¹⁸

Maps of HBV prevalence in different population groups by country in Europe are available in the ECDC Technical Report.⁸

Global distribution

The global prevalence of chronic HBV infection (based on % of population HBsAg positive) is as follows²⁰:



High prevalence (≥8%): sub-Saharan Africa, South-East Asia, the Eastern Mediterranean countries, south and western Pacific islands, the interior of the Amazon basin and certain parts of the Caribbean.

Moderate prevalence (2–7%): in south-central and south-west Asia, eastern and southern Europe, the Russian Federation and most of central and South America.

Low prevalence (<2%): Australia, New Zealand, northern and western Europe, and North America.

Transmission risks

The hepatitis B virus can survive outside the body for at least 7 days.²¹ Several factors influence the risk of transmission of HBV infection, including the viral load of the source.

In a healthcare occupational context, the level that is regarded as "high" for a viral load differs in various regions. In America and Ireland, HCWs who are infected with HBV but have a circulating viral burden $<10^4$ genome equivalents/ml are allowed to continue working unrestricted.^{22,23} Transmission of HBV via a percutaneous route is considered unlikely at HBV DNA levels below 10^7 genome equivalents/ml.²⁴

Needlestick injuries

Those who are e antigen positive generally have higher viral loads, and the transmission rate of HBV following a needlestick injury from a source who is e antigen positive is estimated to be between 30% and 62%. ^{4, 22} The same injury with exposure to blood from a source who is e antigen negative is associated with 6-37% risk of serological evidence of HBV infection in the recipient. ^{4, 22} Some patients are infected with pre-core mutant viruses. This is associated with a high viral load in the absence of the e antigen, and thus is also associated with a high risk of HBV transmission. ²²

The risk from needlestick injuries in the community is more difficult to estimate and the exact incidence of needlestick injuries and the transmission rate is unknown. The limited published case reports^{25, 26} would indicate that there is a very low risk of HBV transmission associated with community acquired needlestick injuries.

Other healthcare setting exposures

Spring loaded lancets have been implicated in the transmission of HBV to patients^{27,} as have reusable sub-dermal EEG electrodes.²⁸ There is a report of transmission of HBV to a patient during an endoscopic procedure, although no biopsies were taken, but bleeding gastric ulceration was identified. The presumed source was HBeAg positive.²⁹

Cleveland et al report that HBV infection prevalence in dentists increases with longer duration in practice. ³⁰Although rates in a reference control population were not included in this report, increasing prevalence with longer duration of practice indicates that there is potential for transmission to dentists during their work.

Other percutaneous exposures

There are case reports documenting the transmission of HBV among butchers.^{31, 32} These are attributed to small hand cuts, and sharing knives, which can carry the virus on the handle. It is also thought that HBV can be transmitted via small cuts acquired in barber shops.³³

Body fluid exposures

HBV DNA has been detected in body fluids apart from blood, including saliva, urine, nasopharyngeal fluid, semen, cervicovaginal fluids and tears. 34-37. HBV transmission can occur following exposure to non-intact skin and mucous membranes. A case report describes transmission of HBV via broken skin, following contact with saliva and nasopharyngeal fluids from the source. 38

Human bites

Case reports have documented HBV virus transmission via a human bite, when associated with the skin being broken.^{39,}

Sexual exposures

HBsAg has been found in seminal fluid and vaginal secretions, although concentrations in these fluids are lower than in blood.⁴¹ The risk of transmission of HBV following sexual exposure depends on the type of exposure, the viral load of the source, and the presence of sexually transmitted infections.⁴² The prevalence of HBV in heterosexuals is increased in those with multiple sexual partners⁴²⁻⁴⁴, and those who have markers for HIV or syphilis.⁴⁵ An infection rate of 18-44.2% is seen in regular heterosexual partners of HBV infected patients ⁴⁶⁻⁴⁸ In addition, female commercial sex workers with a history of having anal intercourse had an increased risk of HBV infection.⁴⁵

The risk of developing HBV infection is particularly high among men who have sex with men. ^{41, 49} For men who have sex with men, the prevalence of HBV infection is increased in those who have a history of an ulcerative sexually transmitted infection, chlamydia, gonorrhoea, commercial sex work, or multiple partners. ⁵⁰ There is also a significant risk associated with unprotected insertive anal intercourse. ⁵¹

Hepatitis B transmission risk by exposure type

Exposure		Risk per exposure (unless otherwise stated)
Needlestick	Healthcare setting, patient known	HBeAg (+) = 37-62% risk of serologic evidence of infection in recipient
		HBeAg (-) = 23-37% risk of serologic evidence of infection, 1-6% clinical infection ⁴
	Healthcare setting, patient unknown, or patient known but serology unknown	Requires risk assessment
	Community setting	2 case reports only. ^{25, 26} Risk very low. Requires risk assessment. For example, if the local PWID population has a seroprevalence of 50%, the risk from a community acquired needlestick is 12-31%. ⁵² (Note: seroprevalence in PWID in Ireland is lower than 50% - see epidemiology section).
Other percutaneous injuries with blood exposure	Healthcare sharp (e.g. lancet)	Risk per exposure unknown. 36.8% ⁵³ -42% ²⁷ developed HBV after repeat exposures.
	Exposure prone procedure by infected healthcare worker	Transmission rates vary between 6 and 15% ⁵⁴ - most were before standard precautions introduced
Transfusion		52-69% transmission if transfused with HBsAg (+) blood ⁵⁵
Human bites		Risk negligible in the absence of visible blood. Case reports only. Requires risk assessment.
Percutaneous exposure to other body fluids (e.g. saliva)		Very low risk. Case reports - HBeAg (+) source. ³⁸ Requires risk assessment.
Sexual exposures	Heterosexual exposures in general	18% ⁴⁶ – 40% ⁴⁷ - 44.2% ⁴⁸ infection rate seen in regular partners of HBV infected people
		Increased risk if: multiple partners ^{42, 44} , syphilis ^{44, 45, 56} , gonorrhoea ⁵⁶ , receptive anal intercourse ⁴⁵
	Men who have sex with men	Increased risk of HBV transmission associated with ulcerative STI, gonorrhoea/chlamydia, sexual partner with HIV/AIDS, multiple sexual partners, commercial sex work ⁵⁰ , history of insertive anal intercourse ⁵¹
	Receptive oral sex (fellatio)	Possible means of transmission ⁵⁷

Risk assessment

- Type/details of injury as above
- Source status increased risk with HBeAg, high viral load
- Recipient status increased risk if immunocompromised
- For unknown source, consider where injury occurred community setting versus hospital setting
 - If in hospital consider high-risk ward/patients
 - If in community consider prevalence of HBV and of PWID locally



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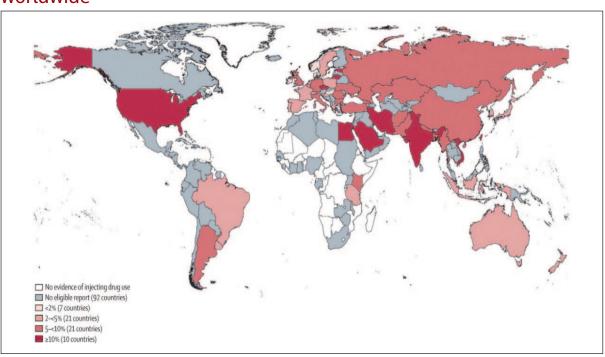


Maps of global distribution of hepatitis B infection

Prevalence of hepatitis B worldwide

Source: Ott JJ, Stevens GA, Groeger J, Wiersma ST. Global epidemiology of hepatitis B virus infection: new estimates of age-specific HBsAg seroprevalence and endemicity. Vaccine. 2012; 30(12): 2212-2219.

Prevalence of hepatitis B surface antigen in people who inject drugs worldwide



Source: Reprinted from Lancet 2011;378(9791), Nelson PK, Mathers BM, Cowie B, et al. Global epidemiology of hepatitis B and hepatitis C in people who inject drugs: results of systematic reviews, pages 571-83, Copyright (2011), with permission from Elsevier.



Hepatitis C virus: epidemiology and transmission risks

Hepatitis C infection is caused by an RNA virus that was first identified in 1989. Chronic hepatitis C infection is a major cause of chronic liver disease and death throughout the world. Approximately 3% of the world's population is infected with hepatitis C virus (HCV). Six distinct but related genotypes and multiple subtypes have been identified. In western Europe genotypes 1a and 1b are most common, followed by genotypes 3 and 2.

Transmission

HCV is transmitted by blood and now occurs primarily through injecting drug use, and less frequently through sex with an infected partner, occupational exposure, and maternal-foetal transmission. In some cases no risk factors can be identified.^{1,5} Transfusion-related HCV infection is rare now since the introduction of routine screening of blood for HCV antibodies in the early 1990s.⁶

Clinical information

In general, acute HCV infection is relatively mild, with only 20-30% of infected persons developing symptoms or clinically evident acute infection. In most persons who become infected with HCV, viraemia persists. Antibody to HCV (anti-HCV) is present in acute, chronic and resolved infection. HCV RNA/HCV Ag is an indication of HCV viraemia.

Chronic HCV infection is marked by persistence of HCV RNA for at least 6 months after onset of infection. Spontaneous resolution after 6 or 12 months of infection is unusual. Between 55 and 85% of those infected develop chronic infection.⁶ Chronically infected people are at risk for progressive liver disease characterised by hepatocellular inflammation, hepatic fibrosis, cirrhosis and hepatocellular carcinoma (HCC). These complications develop only in a proportion of patients and only after many years or decades of infection. It has been estimated that up to 20% of chronically infected individuals will develop cirrhosis of the liver over a 20 to 25 year period, and that, of patients with cirrhosis, approximately 3% to 4% will develop HCC per year. Factors that have been shown to be associated with progression of liver fibrosis include older age at infection, male gender, genetic factors, metabolic factors (steatosis, diabetes and obesity), co-infection with human immunodeficiency virus (HIV) or hepatitis B, duration of infection, and alcohol intake.⁶

Highly effective all-oral treatment with direct-acting antivirals is now available in Ireland. This eradicates the virus in over 90% of cases.⁷

Prevalence of HCV infection in Ireland, Europe and the world

Ireland

A previous study has estimated that the prevalence of chronic HCV infection in Ireland is 0.5-1.2% ⁸. This study took undiagnosed cases into account. More recent estimates of levels of undiagnosed hepatitis C in Ireland indicate the overall prevalence of hepatitis C in Ireland is more likely to be between 0.5 and 0.7% (23,000 to 32,000). ⁹ This is similar to other countries in northern Europe and in line with the WHO estimate of <1%. However, it is more prevalent in certain sub-groups of the population, in particular people who inject drugs (PWID) and prisoners. HCV may also be more prevalent in immigrants to Ireland from endemic countries.

Blood donors

Of 313,019 first time blood donors tested by the IBTS between 1997 and 2015, 48 (0.015%) were found to be HCV positive. (Personal communication, Dr Joan O'Riordan, IBTS, July 2016).

Asylum seekers

Screening of asylum seekers in the HSE eastern region 1999-2003 found a prevalence of anti-HCV of 1.5%.¹⁰ A reception centre in HSE East, reported that 1% of those tested under the voluntary health screening programme, between 2004 and 2012, were positive for chronic HCV infection.¹¹

Prisoners and people who inject drugs

Studies of PWID in prisons and PWID attending methadone clinics, specialist addiction treatment centres and GPs have estimated the HCV prevalence in this population to be between 62% and 81%.¹²

A national cross sectional survey of Irish prisoners in 1998 showed a prevalence of anti-HCV of 37% of all prisoners, and of 81.3% in prisoners who were prisoners who inject drugs.¹³

More recently, a 2011 prison study found that 54% of prisoners with a history of injecting heroin were anti-HCV positive and 41.5% of prisoners with a history of injecting any drugs were anti-HCV positive.¹⁴



Trends in HCV in Ireland

Hepatitis C became a notifiable disease in Ireland in 2004. Between 2004 and 2015, 13,478 cases were notified. The highest annual number of notifications was in 2007 (n=1539). There has been a significant decrease in recent years and 678 cases were notified in 2015. Two thirds of cases were male and most were young to middle aged adults (median age: 34 years, mean age: 36.1 years). Where risk factor information was available, over 80% of cases between 2007 and 2015, were among people who inject drugs.⁹

HCV in Europe

In Europe, HCV infection shows a significant increasing trend in reported numbers. Every year there are 27,000 to 29,000 newly diagnosed cases in the EU/EEA.¹⁵

A recent systematic literature review of HCV prevalence in Europe, based on information from 14 countries, reported a prevalence range of 0.4-3.5%. The prevalence is higher in the southern part of Europe. Countries with high prevalence (more than 2%) include Italy, Romania and Spain. Medium prevalence was observed in Bulgaria, France, Greece, and Poland. Countries with low prevalence (less than 1%) include Belgium, Germany, the Netherlands, Sweden, and the United Kingdom. Sweden, and the United Kingdom.

The most severely affected population groups are people who inject drugs, haemodialysis patients, persons living with HIV, inmates, and immigrants from high-endemic regions. Reported numbers are likely to reflect the current testing and screening practices in countries rather than the real incidence of infection. The reported number is an underestimate of the real occurrence of HCV due to the asymptomatic nature of the infection.¹⁵

Maps of HCV prevalence in different population groups by country in Europe are available in the ECDC Technical Report.¹⁶

Global HCV distribution

The estimated global prevalence of HCV is 2-3%. 17,18 Countries with the highest reported prevalence rates are located in Africa and Asia. China has a reported seroprevalence of 3.2%. One community-based survey in India reported an overall rate of 0.9%. Indonesia's rate is 2.1% in serosurveys of voluntary blood donors. The seroprevalence in Pakistan is reported to range from 2.4% to 6.5%. Egypt has the highest reported seroprevalence rate, 22%. Areas of lower prevalence include North America, northern and western Europe, and Australia.

The predominant source of new HCV infections in developed countries over the past few decades is injecting drug use. In developing countries, unsafe therapeutic injections and transfusions are likely to be the major modes of transmission.¹⁷ Anti-HCV prevalence in PWID globally varies greatly, from 9.8% to 97.4%.¹⁹ (See map, appendix 24).

Transmission risks

Needlestick injuries

There is a wide range of reported estimates for the risk of transmission of HCV after a needlestick or sharps injury from a source patient – between 0 and 10%. ²⁰⁻²² The estimated risk from a needlestick injury from a source with detectable HCV RNA is 6.1%. ²³ The risk of developing HCV is greater after an injury with a hollow-bore needle²¹, or deep injuries²⁴, compared with other injuries. Also, one study showed an 11-fold increase in transmission of HCV from source patients with viral load >6 log10 copies/ml, compared with source patients with viral load $\leq 4 \log 10$ copies/ml following percutaneous exposure. ²⁴ The risk of transmission is also influenced by whether the source is co-infected with HIV (see section below).

In cold temperatures, HCV can survive in syringes for many days in laboratory studies.²⁵ The clinical implications of this are unknown, but the risk of becoming infected with HCV from an abandoned syringe depends on the prevalence of HCV in the local community. There are case reports of HCV transmission from needlestick injuries in the community²⁶, but as the exact incidence of injuries in the community is not known, the risk of transmission from such injuries cannot be accurately quantified.

Other percutaneous exposures

The risk of acquiring HCV during an operation performed by an infected surgeon is reported to be between 0 and 3.7%. ^{27,28,29} In general the risk of contracting HCV following an injury from an unknown source is negligible.³⁰

Sharps in the workplace, other than in the healthcare setting, such as razors and meat slicers have also been implicated in the transmission of HCV. ^{31, 32}

There is an increased incidence of HCV in those who have a tattoo, with a pooled odds ratio of 2.73 (95% CI 2.38-3.15). Large tattoos, and those received in non-professional locations are associated with the greatest risk.³³

Splashes/mucocutaneous exposures

Several case reports have been published describing the transmission of HCV following a splash of blood into the eye of the recipient. 34,35 Also, transmission of HCV has occurred following splashes of infected blood onto broken skin. 36 The exact risk associated with these exposures is unknown.



Exposure to saliva (including injuries caused by human bites)

HCV RNA has been demonstrated in saliva. 37,38 Case reports describe transmission of HCV following human bites, but precise details of the nature of the bites, and whether blood was present in the mouth of the biter, or whether skin was broken at the time of the bite, are not known. 39 Inoculation with saliva has caused transmission of the virus in experimental studies. 40,41

Studies in dentists indicate a low incidence of nosocomial transmission of HCV. 42 It is also thought, however, that HCV can be transmitted via sharing a toothbrush with an index case. $^{38, 43}$

Sexual exposures

In general, transmission of HCV via sexual contact is inefficient in stable monogamous heterosexual couples.⁴⁴ There is evidence, however, of a low rate of transmission of HCV between discordant heterosexual couples and a prevalence of 2-6% of anti-HCV in the non-index partner.⁴⁴⁻⁴⁶ Higher prevalence of anti-HCV has been observed in those with multiple sexual partners, in the absence of other risks, such as PWID or recipients of blood products, as further evidence of the plausibility of sexual transmission.^{47, 48} If a risk is present, it is likely to be very low, and a rate of transmission per heterosexual exposure has not been calculated.

Recent outbreaks of acute HCV among HIV-positive MSM who deny PWID suggest that the epidemiology of HCV transmission is changing in this population. In several European countries as well as in the United States and Australia, HCV has unexpectedly emerged as an STI among HIV-positive MSM. Longitudinal cohort studies have confirmed a marked increase in HCV incidence among HIV-positive MSM, but not HIV-negative MSM, after the year 2000. 49 Studies in Australia, UK, Switzerland and the Netherlands have reported an incidence of HCV infection ranging from 0.6 to 0.9/100 person years in HIV positive MSM who were not PWID. 50

Exposure to other body fluids

HCV RNA has been identified in blood, saliva³⁷, bile⁵¹, sweat⁵², semen⁵³, and cervicovaginal secretions.⁵⁴ The infective potential of cervicovaginal secretions is questioned⁵⁵, but may increase during menstruation.⁵⁴

Transmission of infection following exposure to a source with HIV and HCV

The risk of developing HCV infection after simultaneous exposure to HIV and HCV is estimated at $2.8\%^{56}$ (in this study, no one developed HIV after simultaneous exposure). 100% of patients who received an injection drawn from a vial contaminated with HIV and HCV developed acute HCV infection, but no one developed HIV.⁵⁷

HIV and HCV transmission from a patient to a healthcare worker occurred after contact with the patient's emesis, faeces and urine, to non-intact skin on the healthcare worker's hands.⁵⁸

A case report describes the transmission of HCV, but not HIV, via a human bite to the hand from a source co-infected with HIV and HCV. ⁵⁹ Although the recipient had a wound on his hand prior to the bite, it is not known whether there was blood in the mouth of the source at the time of the incident. Studies have not shown an increased incidence of HCV RNA in saliva of co-infected patients compared to those infected with only HCV. ⁶⁰

The odds ratio of sexual transmission of HCV increased in women co-infected with HIV or another sexually transmitted infection (adjusted odds ratio 3.3-3.9) or homosexual men co-infected with HIV (adjusted odds ratio 4.1-5.7).

There is an increased incidence of HCV-antibodies in patients who had acquired HIV via heterosexual transmission, than in those who had developed HIV from a different exposure. ⁶²

HIV status does not seem to influence the presence of HCV in semen in men co-infected with HCV and HIV. 63 HCV RNA is detected more frequently in cervicovaginal fluid from women co-infected with HIV, than in those not infected with HIV 64 , especially if HCV viremia is present, or if HIV RNA is also found in the cervicovaginal secretions.

Hepatitis C transmission risk by exposure type

Exposure		Risk per exposure (unless otherwise stated)
Needlestick	Healthcare setting, source patient (serology) known	$0-10\%$. $^{20-22}$ Average $1.8\%^{65}$ Increased risk if - hollow needle ²¹ , deep injuries 24 , co-infection with HIV ⁵⁶ , high viral load. 24
	Healthcare setting, source patient unknown, or unable to test source patient (serology unknown)	Unknown source – negligible risk. ³⁰ Risk assessment required
	Community setting	Risk not accurately determined. ²⁶ Risk assessment required. If local PWID population has a seroprevalence of 50-90%, the estimated risk of HCV transmission in a community needlestick injury is 1.62%. ⁶⁶
Exposure prone procedure by infected healthcare worker		0-3.7%. ^{27, 28, 29} Risk may increase to 6% for certain procedures, e.g. open heart surgery. ²⁸ Risk assessment required.
Non healthcare related occupational sharp injuries		Risk not accurately determined, but transmission possible. ^{31, 32} Risk assessment required.
Tattoos		Risk not accurately determined. Pooled odds ratio 2.73 (95% CI 2.38-3.15) ³³
		Risk assessment required. Increased risk if larger tattoos or tattoos in non-professional locations
Mucous membrane exposure to blood		Very low risk. Case reports only. ^{34, 35} Risk assessment required
Intact skin exposed to blood		No recognised risk
Non-intact skin, body fluid exposure		Very low risk. Case report describes transmission of HIV and HCV from co-infected source. 58 Risk assessment required.
Human bite injuries		Very low risk. ³⁹ . Case reports only. Risk assessment required. Possible higher risk of transmission of HCV than HIV if the source patient is co-infected with HCV and HIV. ⁶⁰
Sexual exposures	Heterosexual exposures in general	Inefficient transmission ⁶¹ , but transmission possible as seen in stable heterosexual relationships ⁴⁴⁻⁴⁶ , and in those with history of multiple sexual partners. ^{47, 48} Possible increased risk of transmission if source co-infected with HIV ⁶¹
	MSM	Inefficient transmission. ^{67, 68} Co-infection with HIV increases the risk of transmission ^{61, 69-71}

Note: In England, between 1997 and 2007, there were only 14 reported cases of HCV transmission from a patient to a healthcare worker, with a transmission rate calculated as 1.6%.⁷²

Risk assessment

- Type/details of injury as above
- Source status increased risk with high viral load
- Recipient status increased risk if immunocompromised
- For unknown source, consider where injury occurred community setting versus hospital setting
 - If in hospital consider high-risk ward/patients
 - If in community consider prevalence of HCV and of PWID locally
- Consider where the needle was found and the temperature of environment longer virus survival in cold temperatures thus potential increased risk of transmission.²⁶





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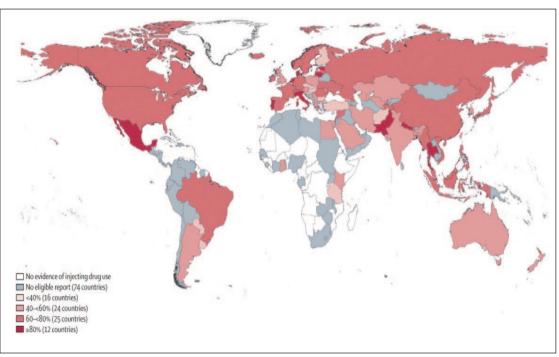


Maps of global distribution of hepatitis C infection

Prevalence of hepatitis C worldwide

Source: Mohd Hanafiah K, Groeger J, Flaxman AD, Wiersma ST. "Global Epidemiology of Hepatitis C Virus Infection; New Estimates of Age-Specific Antibody to HCV and Seroprevalence." Hepatology 2013; 57:1333-1342.

Prevalence of anti-hepatitis C among people who inject drugs worldwide



Source: Reprinted from Lancet 2011;378(9791), Nelson PK, Mathers BM, Cowie B, et al. Global epidemiology of hepatitis B and hepatitis C in people who inject drugs: results of systematic reviews, pages 571-83, Copyright (2011), with permission from Elsevier.



Human immunodeficiency virus: epidemiology and transmission risks

General details

The HIV virus was discovered in 1983. There are currently two groups of viruses which have been isolated (HIV type 1 and HIV type 2), collectively known as HIV (human immunodeficiency virus).² In general, HIV type 2 is not found outside western and central Africa. HIV type 1 is identified globally. Following infection, the host's cells transfer the virus to the local immune system, including T-cells, macrophages and dendritic cells. Within 10-12 days of infection, HIV RNA can be detected in blood by PCR.

During this acute infection (also referred to as primary HIV infection, or the seroconversion illness), HIV RNA levels peak, before declining over subsequent weeks.³ Antibodies to HIV usually develop within 3-5 weeks of becoming infected. The time period between becoming infected and developing antibodies is referred to as the serological "window period".² Following seroconversion, there is an asymptomatic phase of variable duration.^{3, 4} During this time, patients are well. Later in the course of the infection, HIV RNA levels tend to drop. Over the subsequent asymptomatic period, of variable duration, CD4+ lymphocyte levels gradually decrease. If levels of CD4+ lymphocytes drop below 200-350 cells/ μ l, the patient is at increased risk of developing opportunistic infections.

Clinical information

The symptoms of acute HIV infection can last for between 7 and 10 days. The patient may complain of symptoms resembling the "flu", or mononucleosis infection.3 Typical symptoms include fever, maculopapular rash, oral ulcers, lymphadenopathy, arthralqia, pharyngitis, malaise, weight loss and myalqia. Once these acute symptoms resolve, most patient enter an asymptomatic phase. This asymptomatic phase can last more than 10 years.

When CD4+ lymphocyte levels drop below 200-350 cells/µl, the patient is at increased risk of developing opportunistic infections⁵, including pneumocystis pneumonia, oesophageal candidiasis, cerebral toxoplasmosis, and cytomegalovirus, amongst others. These infections, along with cancers such as Kaposi sarcoma, are referred to as AIDS defining conditions.

Treatment for patients with HIV infection is with life-long anti-retroviral drugs. This results in a significant reduction in the amount of virus in the blood, usually to undetectable levels, and allows for immune recovery.

Transmission

HIV has been isolated from semen, cervical secretions, lymphocytes, cell-free plasma, cerebrospinal fluid, tears, saliva, urine and breast milk. This does not mean, however, that these fluids all transmit infection since the concentration of virus in them varies considerably. Particularly infectious are semen, blood, and possibly cervical secretions. The risk of transmission increases with the burden of HIV (i.e. the HIV viral load) in the inoculum.⁷

The commonest mode of transmission of the virus throughout the world is by sexual intercourse. Other methods of transmission are through receipt of infected blood or blood products, donated organs, and semen. Transmission also occurs through the sharing or reuse of contaminated needles by people who inject drugs (PWID) or for therapeutic procedures, and from mother to child. The virus is also transmitted through breast milk. Healthcare workers (HCW) can be infected through needlestick injuries, and skin and mucosal exposure to infected blood or body fluids.

Prevalence of HIV infection in Ireland, Europe and the world

Ireland

HIV became a notifiable disease in Ireland in September 2011. Case based reporting of HIV cases has been in place since 2001. In 2014, a total of 377 newly diagnosed cases were reported in Ireland, a rate of 8.2/100,000. The highest proportion was attributed to MSM exposure (49%), followed by heterosexual transmission (33%), and PWID (7%). Of the 377 cases, 36.3% were born in Ireland and 53.8% were born abroad.8

Annual numbers of new diagnoses of HIV in Ireland have fluctuated between 300 and 400 over the past decade. In recent years there has been a change in the predominant modes of transmission - the annual number of new cases among PWID has decreased each year since 2004, up to 2013; the annual number of cases attributed to heterosexual transmission has decreased from a peak in 2003; and the number of cases in MSM continues to rise year on year since 2005.8



Blood donors

Of 313,019 first time blood donors tested by the IBTS between 1997 and 2015, 14 (0.0045%) were found to be HIV positive. (Personal communication, Dr Joan O'Riordan, IBTS, July 2016).

Pregnant women

HIV screening is offered routinely to all pregnant women in Ireland under a voluntary antenatal HIV testing programme that was introduced in 1999. In 2014, the national reported uptake of HIV antenatal screening (from 17 hospitals) was 99.9%, the rate was 100% in 16 of the hospitals. The HIV prevalence rate among pregnant women in Ireland was 0.15% in 2014, slightly higher than the rate in 2013 (0.14%). The prevalence of HIV infection among pregnant women varied among HSE areas, ranging from 0.05% in HSE West to 0.23% in HSE Dublin Northeast.9

Prisoners and injecting drug users

In 1997, 17% of a group of PWID in the HSE eastern region, who were attending methadone clinics, tested positive for HIV infection.¹⁰ A cross sectional study of 307 opiate users attending 21 addiction treatment centres in the HSE eastern region was carried out in 2001. The prevalence of anti-HIV was 11%. In 2001, the largest tertiary centre for HIV infection in Dublin reported a five-fold increase in new HIV diagnoses in PWID between 1995 and 2000.¹² A study carried out among socially excluded drug users in 10 European cities in 1998-2000 found a self-reported HIV positive prevalence of 24.6% in Dublin, the second highest of the cities.¹³

In 2014, 27 new HIV diagnoses (7%) were among people who inject drugs (PWID), representing a 29% increase in the number of diagnoses in 2013 (21). 89% of the cases were resident in HSE East at diagnosis and many of the infections were recently acquired at time of diagnosis. Injection of newer street drugs, including "snow blow", amongst homeless, chaotic PWID were common factors in these individuals.8

A national cross sectional survey of Irish prisoners in 1998 showed a prevalence of anti-HIV of 2%. The prevalence was 3.5% in prisoners who were PWID.14

Asylum seekers

Screening of asylum seekers in the HSE eastern region 2000-2003 found a prevalence of anti-HIV of 2.2%. 15

HIV infection in Europe

In 2013, 29,157 HIV diagnoses were reported by 30 EU/EEA countries with a rate of 5.7 / 100,000 population. The male-to-female ratio was 3.3. Young people aged 15-24 accounted for 11% of all HIV diagnoses reported by this varied widely from 6% in Norway to 25% in Romania.¹⁶

MSM accounted for 42% of diagnoses while heterosexual transmission accounted for 32%. Transmission due to injecting drugs accounted for 5% of diagnoses and for nearly 20% of the cases, the transmission mode was unknown.16

Global HIV distribution

At the end of 2010, an estimated 34 million people were living with HIV globally. The annual number of people newly infected with HIV continues to decline, although there is stark regional variation. In sub-Saharan Africa, where most of the people newly infected with HIV live, the incidence peaked in 1996-1998. However, the annual number of people newly infected with HIV has risen in the Middle East and North Africa in the past decade. And in Eastern Europe and Central Asia, where the incidence had slowed drastically in the early 2000s, the incidence has been accelerating again since 2008.17

The prevalence of HIV among adults (15-49 years) by world (WHO) region is estimated to be as follows: Africa (4.5%), Americas (0.5%), Eastern Mediterranean (0.1%), European (0.4%), South-East Asia (0.3%), Western Pacific (0.1%).¹⁸

Estimates of HIV prevalence globally among those with a history of PWID vary. 19 This paper by Mathers et al presents detailed tables of prevalence of PWID and of HIV in PWID by world region. The largest numbers of injectors were found in China, the USA and Russia, where mid-estimates of HIV prevalence among injectors were 12%, 16% and 37% respectively (see maps, appendix 26).



Transmission risks

Needlestick injuries

Following a needlestick injury with a needle contaminated with blood from a source known to have HIV, the risk of becoming infected with HIV is thought to be between 0.1% and 0.36%.^{20, 21-23} The risk from needlestick injuries in the community is more difficult to estimate and the exact incidence of needlestick injuries and the transmission rate is unknown. Intravenous drug injections carry a higher risk, with the risk of HIV transmission estimated to be between 0.63% and 2.4% per injection.²⁴ The risk from a community needlestick where the source is unknown is estimated to be between 0.003 and 0.05%, if the local PWID seropositivity is approximately 1%.²⁵

Several factors influence the rate of transmission. In a study of occupationally associated needlestick injuries, seroconversion was associated with factors including whether the needle or device was visibly contaminated with blood (odds ratio 10, 95% CI 4.6-23), the injury was deep (OR 15, 95% CI 8-26), or if the injury was sustained by a large gauge hollow bore needle (OR 14, 95% CI 4.9-39).²² The health of the source patient is also relevant. If the source patient has AIDS, the odds ratio for transmission of HIV is 1.9 (95%CI 0.8-4.6). It has been demonstrated that if the source patient died within 2 months of the needlestick injury, the odds ratio for transmission increased to 4.8 (95% CI 2.3-10).²²

Post-exposure prophylaxis (PEP) is thought to reduce seroconversion by up to 81% (95% CI 48-94%).²² Commencing PEP early after the injury provides the greatest benefit. In animal studies, administration of PEP within 36 hours prevented seroconversion. In animals who received PEP at 72 hours after exposure, 25% seroconverted. In contrast, 75% of the animals who did not receive any PEP seroconverted by 4 weeks post exposure.²⁶ Additionally, treatment is most effective when continued for 28 days. There are documented case reports of HCWs who have become infected with HIV following occupational exposure, despite use of PEP, which in one case was commenced within 30 minutes.²⁷

Blood splashes

The risk of transmission associated with splash injuries is less than the risk associated with needlestick injuries, and HIV seroconversion following splashes of blood to intact skin has not been reported.23 The risk of HIV transmission associated with exposure of non-intact skin and mucous membrane exposure to HIV infected fluid is possible²⁷, but the risk is very low.²³ Pooled data provided an estimated risk for transmission of HIV via mucous membrane exposure at 0.09%, based on one seroconversion from more than 1000 documented exposures.²¹

Human bites

Infection with HIV after a bite from a patient with HIV "is biologically possible, but remains unlikely".²⁸ Cases of transmission have been reported in case reports, but the exact risk of transmission is unknown, and thought to be very low.^{29,30} In the cases reported, blood was present in the mouth of the biter, and the skin of the recipient was broken. PEP is recommended if a patient has been bitten by someone known to be HIV-positive, with a high viral load, if the bite breaks the skin.31

Although there are reports of HIV transmission from a dentist who had AIDS to patients, it has never been demonstrated that the dentist acquired HIV from any of his patients.^{32, 33} Cases of other dentists and dental health practitioners who developed HIV after presumed occupational contact are reported, but no evidence exists to demonstrate the exact mode of transmission.³⁴ Given that injuries to dentists during procedures are common, at a reported rate of 0.9 per 1000 procedures³⁵, and there are no documented transmissions of HIV to dentists from patients, the rate of transmission overall is very low.

Sexual exposures

The risk of transmission of HIV following sexual exposure depends on the type of exposure, the viral load of the source, the susceptibility of the host, and the presence of sexually transmitted infections in either the source or the recipient. If the index partner also has a genitourinary infection, for instance, the risk of transmission is approximately doubled.³⁶ If the recipient has a genitourinary infection, the risk of acquiring HIV is also elevated.³⁷ Effective antiretroviral therapy has been shown to be protective in preventing sexual transmission of HIV in a landmark randomised controlled trial 38 and a "real world" cohort study. 39 The PARTNER study has demonstrated this to be true in male/female and male/male sexual encounters across a range of sexual activities, including unprotected receptive vaginal and anal intercourse.

Heterosexual exposures

Overall the risk of transmission of HIV, per unprotected coital act, for receptive vaginal sex and insertive vaginal sex is 1 in 1000 and 1 in 1219 respectively. 40 Correct use of a condom reduces the risk of transmission by 93%-100%. 37,41 Circumcision has been shown to significantly reduce HIV acquisition in heterosexual males in high prevalence settings. 42 The risk of



transmission is greater during the initial two and a half months of infection.^{36,43} The cumulative incidence of transmission of HIV to females in couples who practice unprotected anal intercourse is reported as 27.8%, compared to 11.7% transmission to females who do not report anal intercourse.³⁷ Transmission is very unlikely if the source of the exposure is on effective antiretroviral treatment. 38, 39

Men who have sex with men (MSM)

Overall the risk of transmission of HIV, per unprotected coital act, for receptive anal sex and insertive anal sex is 1 in 90 and 1 in 666 respectively.⁴⁰ An Australian cohort study has estimated the per coital risk of HIV to be lower in circumcised MSM (0.11, 95% CI 0.02 - 0.24) versus uncircumcised MSM (0.62, 95% CI 0.07 - 1.68. 44 Transmission is very unlikely if the source of the exposure is on effective antiretroviral treatment.39

Orogenital exposures

The risk associated with orogenital contact cannot be accurately predicted, and is considered low, but not zero. 45

Body fluid exposure

The risk associated with exposures to non-blood stained body fluids is thought to be lower than the risk associated with blood exposures.²⁰ HIV has been identified in semen, but this is reduced if the index patient is on treatment and blood HIV RNA is detected at <400 copies/ml. 46 HIV DNA has been extracted from CSF47 and synovial fluid. 48 Other fluids which it is thought could be implicated in HIV transmission are pericardial fluid, amniotic fluid, peritoneal fluid, human breast milk, vaginal secretions and pleural fluid. Unless there is visible blood present, faeces, vomitus, urine, nasal secretions, saliva, sputum, sweat and tears are not thought to have any infectious potential.⁴⁹

HIV transmission risk by exposure type

Exposure		Risk per exposure (unless otherwise stated)	
Needlestick	Healthcare setting, source patient (serology) known	0.1-0.36%. ²¹⁻²³ Increased risk if large gauge needle, hollow needle, deep injury, visible blood on the device, needle was in patient's artery/vein, or if the source patient has AIDS (or terminal illness).	
	Healthcare setting, source patient unknown, or unable to test source	Risk assessment required of the type of injury and the likely infection status of the source.	
	Community needlestick	Overall low risk and requires a risk assessment of the type of injury, location of the discarded needle (for example if discarded in a location where PWID are known to inject), likely age of the discarded needle and the background prevalence of HIV in the local population.	
Mucous membrane exposure to blood		0.09% ²¹	
Intact skin exposure to blood		No risk ²³	
Human bite		Very low risk. ²⁹ Risk assessment required. Only risk if blood in the mouth of the biter, and significant injury. No risk if no blood in mouth of biter, and exposure to saliva only. Case report suggests that if source co-infected with HCV, HCV transmission more likely than HIV transmission. ⁵⁰	
Sexual exposure	Heterosexual exposure (general)	If source on antiretroviral therapy with suppressed viral load transmission rate = 0 (if viral load < 400 copies/ml) 38,39 Increased risk if source patient has recently seroconverted, e.g. within 2.5 months of seroconversion risk of transmission is estimated to be $0.0082/\text{coital}$ act (95% CI $0.0039-0.015$).	
	Receptive vaginal intercourse	Overall risk is 1 in 1000, which is increased in the presence of cervical ectopy, genital tract trauma, menstruation, genital ulcerative disease (in either partner), infectious syphilis and pregancy. ⁴⁰ Male circumcision reduces HIV acquisition. ⁴²	
	Insertive vaginal intercourse	Overall risk is 1 in 1219. ⁴⁰	
	MSM unprotected receptive anal intercourse	Overall risk is 1 in 90, increased risk if there is ejaculation within the rectum. 40 The PARTNER study has demonstrated zero transmissions in HIV serodiscordant couples where the HIV positive individual is on effective antiretroviral therapy. 39	
	MSM unprotected insertive anal intercourse	Overall risk is 1 in 666. ⁴⁰ The PARTNER study has demonstrated zero transmissions in HIV serodiscordant couples where the HIV positive individual is on effective antiretroviral therapy. ³⁹	
	Orogenital contact	Overall very low risk, estimated to be <1 in 10,000 for both receptive and insertive oral sex. ⁴⁰	

Remember

- There are only 5 reported cases of confirmed HIV transmission from a patient to a healthcare worker in the UK.⁵¹
 There have been no such transmissions between 2004 and 2013, in the UK.⁵²

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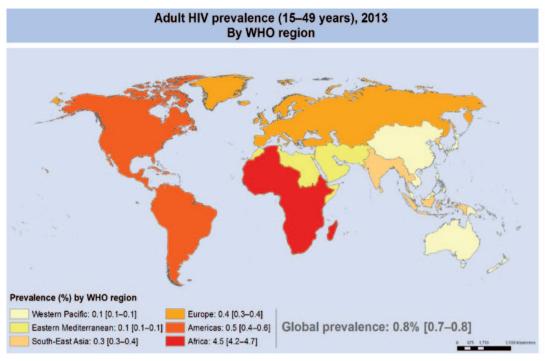


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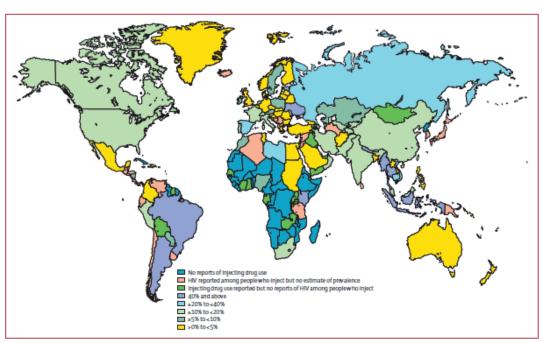
Maps of global distribution of HIV infection

Prevalence of HIV worldwide

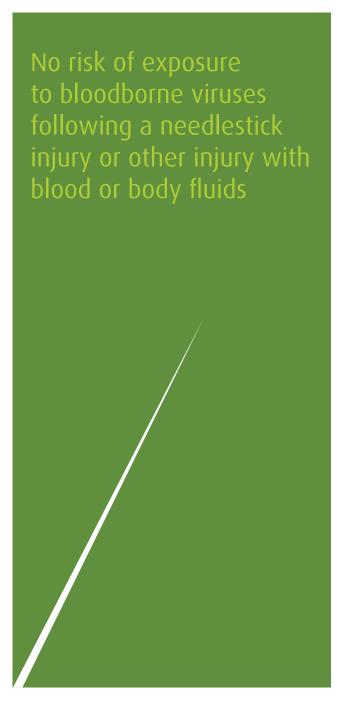


Source: World Health Organisation, 2014.

Prevalence of HIV infection among people who inject drugs

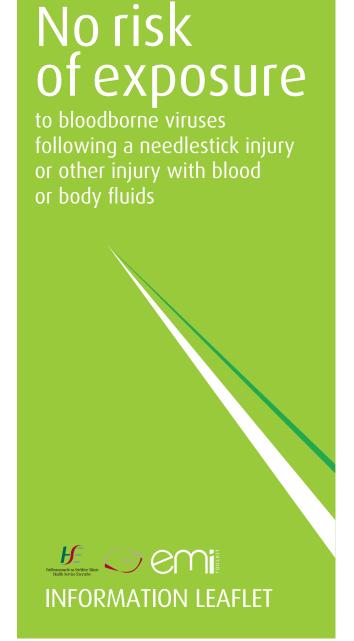


Source: Reprinted from Lancet 2008;372(9651), Mathers BM, Degenhardt L, Phillips B, et al. Global epidemiology of injecting drug use and HIV among people who inject drugs: a systematic review, pages 1733-45, Copyright (2008), with permission from Elsevier.



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I was exposed to blood or body fluids from another person, what is the chance that I will develop an infection?

A doctor has looked at your injury and taken a detailed history from you on how you got your injury. Based on this information, you are not at risk of getting a bloodborne virus such as hepatitis B, hepatitis C or HIV.

What do I have to do next?

If you have a wound, for example, after a needlestick injury or a bite injury, follow the wound care advice that was given to you. Keep the wound clean and dry by keeping it covered with a plaster or bandage until it is healed.

If your wound was caused by a human bite, an antibiotic will be prescribed for you.

Make sure you finish the full course of the antibiotic.

If you have any concerns about your wound after discharge, please attend your own GP for follow up. The emergency department will be sending a letter to your own doctor informing them about your injury and what treatment you received.

I was injured by a needle and I kept the needle – can it be tested for blood or infections?

Testing of needles for blood or infections is of no benefit as it is not very reliable and it can be hard to test for bloodborne viruses. Therefore, it is not recommended.

The needle that you have needs to be carefully disposed of into a special bin so that it will not cause any more injuries. Ask a member of staff about safe disposal of the needle.

Am I allowed to be a blood donor?

Based on your injury, there is no risk that you will get a bloodborne infection from this injury. Therefore, you can be a blood donor. However, the Irish Blood Transfusion Service (IBTS) donor guidelines require a deferral period before donating. For further information, contact IBTS.

Is there any other follow-up that I should know about?

If you are at risk of getting an injury with blood or body fluids again, you may be advised to get a vaccine against hepatitis B.

If you received the 1st dose of hepatitis B vaccine in the emergency department or occupational health department, you will be given instructions about when you should get the next two doses of the vaccine. A hepatitis B vaccination card will be given to you as a reminder of when you should get the next dose of the vaccine.

'If you have any concerns about your wound after discharge, please attend your own GP for follow up.'

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What is the chance I will develop an infection?

Hepatitis B

If someone is exposed to blood infected with hepatitis B virus, e.g. needlestick injury, the transmission rate can be as high as 30%. For this reason, your hepatitis B immune status will have been considered. If you are thought to be not immune to hepatitis B infection, you will be offered vaccination – either completion of the course if you already had one or two doses, or the first of three doses of the vaccine if you have never been vaccinated against hepatitis B. In some circumstances, people may also be offered hepatitis immunoglobulin.

Hepatitis C

Following exposure to blood infected with hepatitis C virus, e.g. needlestick injury, the risk of developing an infection is about 1.8%.

HIV:

Only about 0.3% of those who report a needlestick injury from a patient known to be infected with HIV will develop HIV. The risk of infection following exposure to a splash of blood to your eye or into your mouth is lower, about 0.09%. Exposure to other body fluids is associated with an even lower risk. There is no risk associate with blood exposure to intact skin.

The management of your injury is considered on an individual basis depending on the nature of the injury.

If I do not know, for example, who used the needle before my injury or do not know who injured or assaulted me, does this change my treatment?

You reported an exposure to blood and body fluids from an "unknown source". In this circumstance, it is not possible to exclude the possibility of infection. The risk that you may develop an infection, however, is lower than the risk highlighted above.

What happens next?

You should have been given follow-up appointment dates, or advised how to access follow-up appointments. Follow-up appointments are necessary in order for you to receive test results, get additional blood tests done or receive further hepatitis B vaccinations. It is important that you attend all follow-up appointments. Take note of follow-up appointment instructions at the back of this leaflet. If you have been given hepatitis B vaccine, a hepatitis B reminder card will be given to you.

Is there anything I need to do while I wait for results of the blood tests?

The follow-up is not complete until 3 months after the injury. In the mean time, if you develop symptoms such as fever, any rash, sore throat, swollen glands, mouth ulcers, diarrhoea, joint or muscle pain, headaches, nausea or vomiting, reduced appetite, weight loss or fatigue, please contact your doctor and arrange a review appointment.

Am I allowed to be a blood donor while I am waiting on the results?

You should avoid donating blood or other body fluids, tissues or organs, for the duration of the follow-up period, to limit the risk of passing on any possible infection.

Are there any other additional precautions that I need to take?

Depending on the nature of your injury, additional precautions may also be necessary.

- Pregnancy and breastfeeding should be avoided if possible.
- Do not share toothbrushes, razors or needles.
- Adopt safer sex practices i.e. use a condom for the next three months.
- There is no need to restrict your work practices while awaiting the results of these blood tests.

If you have any concerns regarding this advice or wish to receive counselling, please discuss this with your doctor.

Where will I be attending for my next appointment (including contact details)?	
When is this appointment?	



CHECKLIST



Testing of source person or recipient for hepatitis B/hepatitis C/HIV

This is a checklist for the doctor or nurse providing information to the source or recipient for consent prior to testing. ☐ Explain why a blood test is required in this blood and/or body fluid exposure incident/event ☐ Discuss purpose of test as applicable • Establish baseline status of recipient • Establish infection status of source person Follow-up blood test ☐ Document individual's personal risk for hepatitis B, hepatitis C or HIV ☐ Specify what blood tests are to be done • Hep B surface antigen ± Hep B e antigen, Hep B e antibody, Hep B viral load, • Anti-HBs (if previously vaccinated and no record of post-vaccination titre) Anti-HCV ± Hep C viral load HIV Ag/Ab ± HIV viral load ☐ Discuss advantages of testing and implications of positive test result with individual, covering the following: • Identification of previously unknown disease and ensuring referral to infectious diseases specialist Protection of sexual partners • Allowing informed planning for the future • Possible requirement to inform insurer of a positive test result as is applicable for an existing policy or for a new application · Applicable safe work practices including reporting to own Occupational Health Service Sharing of toothbrushes, shaving or razor blades, needles • Donation of blood, body fluids or other tissues – need to disclose positive results Pregnancy and breastfeeding ☐ Explain confidentiality in the use of and communication of results $\ \square$ Explain that results on source patient may have to be disclosed to recipient ☐ Ensure plan in place to obtain blood results and notify patient of results ☐ Affirm that declining consent will not impact on ongoing care (if applicable) ☐ Offer individual opportunity for clarification of any concerns ☐ Document in presence of patient that informed consent has been given before testing ☐ Inform the patient that hepatitis B, hepatitis C and HIV are notifiable diseases and

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positive results will be notified confidentially to the Medical Officer of Health

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Testing for hepatitis B, hepatitis C & HIV

Source information leaflet









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Introduction

An incident has occurred in which another person became exposed to your blood or body fluid. Because of the nature of the exposure, there is a need to carry out a blood test to check if you have certain viruses that can be transmitted if present in your blood. These viruses are hepatitis B, hepatitis C and human immunodeficiency virus (HIV). A negative test result will reduce the other person's anxiety and eliminate the need for them to undergo unnecessary treatment.



Testing for the viruses

A blood test will be carried out on you in order to assess if you already have these viruses.

The result of this test will be treated as <u>confidential</u> and used only for the purposes of confirming your infection status at the time of the incident. If your test is positive and this was previously unknown to you, the results will be sent <u>confidentially</u> to your own doctor whose name you provided. The results of your blood test may have to be disclosed to the person who was exposed to your blood or body fluid.

What does the blood test involve?

Before the test, you will be provided with information to allow you to give your informed consent to the test. You will not be tested without your given consent. It is similar to a normal blood test that you may have had before. It should only take a few minutes and you will be advised when to expect the results. You have the right to refuse to be tested. If you choose not to be tested, your care will not be affected.

What happens if the blood test is negative?

This means that you tested negative for the viruses at the time of the blood test. No further testing will be required.

What happens if the blood test is positive?

In the event that the blood test is positive for one of these viruses and this was previously unknown to you, you will be referred to a specialist for follow-up. Your own doctor will receive a confidential letter outlining your results.

Are there any implications of a positive test?

- If the test is positive for any of these bloodborne viruses, you will be referred to a specialist for follow up assessment and management.
- Depending on the type of insurance policy, you may be required to inform your insurer that you have tested positive for any of these bloodborne viruses where you have an existing policy or when making a new application
- You will have to inform your sexual partner(s) and you should have been given advice regarding the need for safer sex practices.
- You will need to inform relevant agencies if you are considering donating blood products or other body tissues.
- You should not share shaving blades or razors, toothbrushes and needles.
- You should get expert advice about pregnancy and breast feeding.
- Hepatitis B, hepatitis C and HIV are notifiable diseases and positive results will be notified confidentially to the medical officer of health.

Counselling

If you have any concerns regarding this advice or wish to receive counselling, please discuss this with your doctor.

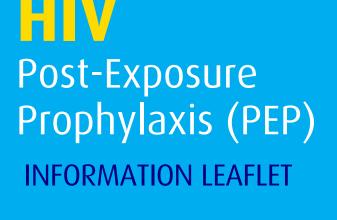
It is similar to a normal blood test that you may have had before. It should only take a few minutes and you will be advised when to expect the results.

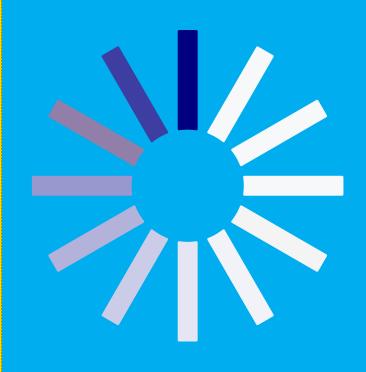


HIV PEP must be taken within 72 hours of your exposure as it will not be effective if taken after 72 hours.

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What is HIV PEP treatment?

HIV PEP is a post-exposure prophylactic (PEP) treatment that is prescribed for you in order to prevent HIV infection following a high risk exposure to blood or body fluids. **The treatment is for 28 days if you are prescribed the full course.** It is very important that you do not miss any doses and complete the 28 day course.

If you attended the emergency department, you will have been given a starter pack of the medications that you will need to take.

In the starter pack there will be only enough medications for 3-5 days. Before the pack has finished you should have been seen by an appropriate specialist. It is very important that you attend all appointments that are arranged for you.

Do I have to take HIV PEP?

Based on your type of injury and the potential risk of HIV being transmitted to you from the source person/ item, it is recommended that you start this treatment immediately.

HIV PEP should be taken as soon as possible after your exposure. It will not be effective if taken after 72 hours.

If you are HIV positive on your first blood test, your HIV PEP medication will be reviewed.

How long will I be on this treatment?

Generally the treatment will last 28 days and will depend on an assessment by the specialist. You will also require follow-up blood tests over the next four months. Follow up blood tests will be arranged by the clinic before you leave.

What medications will be prescribed?

You will be prescribed medications called Truvada® and Isentress®, or Truvada® and Tivicay®. If you are pregnant or may become pregnant it is important that you let the person prescribing PEP know. In general, Tivicay® is not recommended for use in early pregnancy.

You should take one blue tablet of Truvada® once a day with food. You should take one pink tablet of Isentress® twice a day – take them 12 hours apart if you can. You should take one yellow tablet of Tivicay® once a day. It is important that you take your tablets at the same time each day and don't miss any doses. Set reminders on your phone to ensure that you take the medication on time.

Are there any side effects to taking these medications?

Yes, they can cause diarrhoea, vomiting, tiredness and headaches. Side effects usually disappear after a few days but if they worsen talk to your doctor and you may need to take time off work or study.

Are the HIV PEP medications safe to take with my own medications?

If you are already on medication for other medical conditions, it is really important to let the doctor/pharmacist giving you PEP know. They will advise you if your own medications are safe to take with the HIV PEP treatment. It is not recommended to take Isentress® with certain antacids (those containing aluminium and/or magnesium). Talk to your doctor about other antacids you can take.

Are there any special precautions to be taken whilst I am on this treatment?

- Do not share toothbrushes, razors or needles.
- Adopt safe sex practices i.e. use a condom for the next three months.
- If you are pregnant or breastfeeding you must seek advice from an obstetrician or HIV/infectious diseases specialist.
- It is not recommended for you to donate blood or other body fluids for the duration of your treatment and follow-up care.

Follow-up Care

It is very important that you attend all your appointments. You should be seen in a specialist clinic before the starter pack of medication runs out. A referral letter will be sent to the appropriate specialist explaining the treatment that you received. It is useful to take note of the following:

Where will I be attending for my next		
appointment (including contact details	?)	
When is this appointment?		

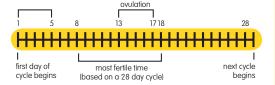
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Fertility

Lots of people do not know when a woman is most fertile during her cycle (in other words, when pregnancy is most likely to occur).

A woman releases an egg (ovulates) every month 12-16 days before the onset of her next menstrual period. This is the most fertile time of her menstrual cycle. The time that ovulation occurs within each cycle can vary. It can depend on length of the cycle and on a range of external factors over which a woman may have no control. Examples of external actors could be stress, travel or illness.

*This diagram is based on a 28 day cycle and should only be used as a guide. For more information on fertility, talk to a GP or Family Planning Clinic.



Where women have regular, 28 day cycles, ovulation occurs around the middle of her cycle. As the egg can survive for approximately 12-24 hours and sperm may survive forbetween 5-7 days inside the female body, the fertile time can extend from 7-10 days each month. If a couple have sexual intercourse or intimate sexual contact during this fertile time the egg may be fertilized by a single sperm.

Many women have irregular cycles, so it can be difficult to identify their likely fertile time in each cycle. Every woman's menstrual cycle is unique to her. If a woman has sex without using contraception, she may become pregnant, even at a time in her cycle when she thought she was safe.

Please note that this is general information about fertility which does not replace medical advice. If you need further information about fertility, talk to your local GP.

Your guide to choosing the right contraception for you.

When it comes to your sexual health, nobody else is going to do the thinking for you. It's important then to choose contraception that fits your situation and lifestyle.

In this leaflet, you'll find info on how to protect yourself and your partner from having an unplanned pregnancy and how to prevent against sexually transmitted infections (STIs), You'll also find descriptions of the main types of contraception available. Read on and then have a chat with your doctor and your partner about what's best for you. And remember, above all, to always think contraception. All the methods are very effective – and most are 99% effective – when they are used correctly and consistently.

Remember, only abstaining from (avoiding) all sexual contact offers 100% protection from pregnancy and STIs.

Disclaimer

The information in this leaflet has been supplied by the Crisis Pregnancy Programme in December 2015. It has made every effort to ensure that the information is accurate before going to print. Please remember, however, that the information in this leaflet does not replace medical advice, diagnosis or treatment. If you have questions or concerns or need further information, visit your GP, pharmacist (chemist) or local family planning clinic for professional advice.

About the HSE Sexual Health and Crisis Pregnancy Programme

The HSE Sexual Health and Crisis Pregnancy Programme is a section of the Health Service Executive that is responsible for implementing national strategies that promote sexual health and address STIs and crisis pregnancy in Ireland.

Age of consent

The age of sexual consent in Ireland is 17 years.

Top tips

- Think contraception before you think about having sex! Most contraception methods are 99% effective when used correctly and consistently. However, only abstaining from (avoiding) all sexual contact offers 100% protection from pregnancy and STIs.
- Different contraceptives suit different people. Discuss your contraceptive choices with your GP. You may need to experiment to find the best contraception for you.
- There are long acting methods of contraception available that can be more reliable as they do not require you to take a pill every day e.g. the coil, the implant. More young adults are using these methods of contraception nowadays. These methods can be less expensive in the long run.
- Have an STI check up and discuss contraception with your partner before you get intimate.
- Using 'dual protection' (condoms with another method of contraception) will help you to have safer sex.
- Approximately 80% of 18–24 year olds used contraception every time they had sex, so plan ahead and carry contraception.
- Be prepared research has found that the most common reason why people fail to use contraception is because sex is unplanned or they were unprepared
- Condoms offer the best protection from pregnancy and sexually transmitted infections (STIs) - Johnny's got you covered.



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Intrauterine contraception (IUS and copper coil)

how do they work?

The IUS is a small plastic device that is put into the womb and releases the hormone progesterone. The copper coil is a small copper device that is put into the womb.

Intrauterine contraception works in several different ways - by stopping sperm from meeting the egg, by delaying the egg getting to the womb or by preventing the egg from implanting in the womb.

how effective is it?

This is a highly effective method (more than 99% effective).

things to know before choosing this method

- Works as soon as it is inserted and can stay in place for three to five years
- Can only be inserted and removed by a specially trained doctor
- The IUS may cause irregular bleeding for the first few months but after that time most women have lighter periods and often no periods. The copper coil may cause heavier periods in some women
- · Does not protect against sexually transmitted infections
- It is important that you talk to a doctor who will assess what contraceptive option is best for you



The implant

how does it work?

The implant is a small flexible rod that contains the hormone progestogen. It is inserted under the skin of the upper arm.

It works mainly by stopping the woman from producing an egg. It also thickens the fluid at the neck of the womb and thins the lining of the womb.

how effective is it?

This method is highly effective (over 99%).

things to know before choosing this method

- Lasts for up to three years
- Can only be inserted and removed by a specially trained doctor
- May cause irregular bleeding
- · Does not protect against sexually transmitted infections
- It is important that you talk to a doctor who will assess what contraceptive option is best for you



Progesterone-only pill: the mini-pill

how does it work?

This pill contains one female hormone (progesterone) and is taken every day without a break. It works mainly by preventing sperm from getting through the fluid at the neck of the womb. It may also thin the lining of the womb, which prevents an egg from implanting there and may prevent an eag being released.

how effective is it?

Effectiveness depends on careful and consistent use

The mini-pill is 96-99% effective with very careful use, but it must be taken at the same time every day.

things to know before choosing this method

- · Available only with a prescription
- · Useful for women who cannot or do not want to take oestrogen
- Can be used when breastfeeding
- May cause irregular periods
- Does not protect against sexually transmitted infections
- It is important that you talk to a doctor who will assess what contraceptive option is best for you



Injectable contraception: the hormone injection

how does it work?

A woman receives an injection of a single hormone (progesterone) every 12 weeks. The hormone works mainly by stopping the woman from producing an egg.

how effective is it?

This method is very effective (over 99%) once the injection is given regularly.

things to know before choosing this method

- Injection must be given by a doctor or a nurse
- Useful for those who find it hard to remember to take a pill every day
- May cause irregular bleeding
- Not suitable for long term use
- Does not protect against sexually transmitted infections
- It is important that you talk to a doctor who will assess what contraceptive option is best for you



Condom: Male and Female

how does it work?

This barrier method works by preventing the man's sperm from meeting the woman's eag

The male condom is rolled onto a man's erect penis before sex.

The female condom lines the woman's vagina.

how effective is it?

Effectiveness depends on careful and consistent use.

With careful use, the male condom is 98% effective

and the female condom 95% effective.

things to know before choosing this method

- Widely available for sale without a prescription
- Helps to protect both partners from sexually transmitted infections, including HIV
- Can be used with hormonal contraceptives for additional protection
- Must be correctly and consistently used using condoms properly requires practice.
- It is important to talk to a doctor who will assess what contraceptive option is best for you



Combined oral contraception: the pill

how does it work?

This pill contains two female hormones (oestrogen and progesterone) and is taken every day for three weeks of each month. It works mainly by stopping the woman from producing an egg.

how effective is it?

If properly used, it is over 99% effective. It is less effective with less careful use. It must be taken around the same time every day.

things to know before choosing this method

- Not available without prescription
- Not suitable for women with conditions such as high blood pressure, migraine or smokers over 35
- Vomiting, diarrhoea and taking some medicines such as some antibiotics can interfere with how it works
- Does not protect against sexually transmitted infections
- It is important that you talk to a doctor who will assess what contraceptive option is best for you



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STI screening

It is good sexual health practice to get an STI check regularly. Your doctor can arrange tests for you or you can visit a family planning clinic or an STI clinic.

What happens at an STI clinic?

You will need to make an appointment for most clinics, unless they provide a drop-in service. You don't have to be referred by your GP.

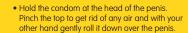
The length of time that you will be at the clinic can vary. If you have no symptoms it tends to be shorter and if you have a specific problem, it may take a bit longer. STI clinics tend to be busy places and you may be waiting for a while to be seen. You will be asked questions about your sex life. Doctors and nurses working in STI clinics are there to help and they have heard it all! It's a good idea to be honest in your answers and worries - don't worry about shocking them - they've heard it all before! Then you will have a series of tests. Blood tests are used to test for HIV, Hepatitis B and syphilis. Swabs and urine are used to examine material from a discharge or an infected area.

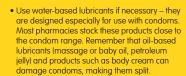
Sometimes you will get some of your results and treatment on the same day. After you've had your tests and treatment (if necessary), you'll be told how results will be made available to you. It's important that you know how results are communicated to you. It's also important that the contact details that you give to the clinic are correct otherwise they won't be able to contact you.

How to use a male condom

Condoms are the most common form of contraception used by 18-24 year olds. Male condoms are really effective when they are used properly. They protect against most (but not all) STIs. It takes a little practice to use one properly – here are some tips.

- Make sure you buy a good quality condom.
 Look for the BSI Kitemark or CE mark and check
 the expiry date.
- Be careful that condoms don't tear when you open the packet – don't use your teeth and be careful with long nails and jewellery.
- Put the condom on before there is any genital contact or penetration – there can be semen on the penis before ejaculation.
- Don't try to put a condom on if the penis is not hard





- When pulling out after sex, hold the base of the condom. Be careful when removing the condom so that you don't spill any semen. There will still be semen on the penis, so keep it away from the vagina.
- Wrap the condom in a tissue and dispose of it safely and hygienically (not down the toilet).

A variety of condom types are available. If one condom doesn't feel comfortable, check out other condom options



The patch

ow does it work?

The patch is like a thin plaster that contains two hormones (oestrogen and progesterone). A woman wears the patch for three weeks out of every four.

In this way, it works like the combined oral contraceptive pill.

how effective is it?

This method is 99% effective when used correctly.

things to know before choosing this method

- Available only with a prescription
- Has the same effects as the combined oral contraceptive pill
- Costs more than the pill
- Timing may be easier to remember (patch replaced once a week)
- Does not protect against sexually transmitted infections
- It is important that you talk to a doctor who will assess what contraceptive option is best for you





The vaginal ring

how does it work?

The ring contains two hormones (oestrogen and progestogen) and is inserted into the vagina for three weeks of every month. It works like the combined oral contraceptive pill.

how effective is it?

This method is 99% effective when used correctly.

things to know before choosing this method

- Available only with a prescription
- \bullet Can be inserted by the woman herself
- Has the same effects as the combined oral contraceptive pill
- · Costs more than the pill
- Timing may be easier to remember (inserted once a month)
- Does not protect against sexually transmitted infections
- It is important that you talk to a doctor who will assess what contraceptive option is best for you

Your guide to emergency contraception

If you've taken a chance or your contraception has failed, you could be at risk of getting pregnant.

What is emergency contraception?

Emergency contraception is a secondary method or 'back-up' contraceptive. It can be used if you want to avoid an unplanned pregnancy after you have had sex without using contraception or if contraception has failed (e.g. the condom slipped or you missed a pill). Emergency contraception is more effective the sooner you take it after having unprotected sex.

Emergency contraception does not provide any protection from sexually transmitted infections (STIs). To get advice on STI testing visit **thinkcontraception.ie**.

It's important to think about using a regular method of contraception. For information about contraceptive options visit **thinkcontraception.ie**



Emergency contraception is more effective the sooner you take it after having unprotected sex.

Emergency contraception facts

- Women of all ages can use emergency contraception to prevent unplanned pregnancy if they have had sex without using contraception or their contraception has failed.
- Many women who have had a crisis pregnancy did not think to use emergency contraception.
- Emergency contraception is not suitable as a regular method of contraception and it does not prevent pregnancy in every woman.
- Many women believe that emergency contraception can only be taken 3 times in their lifetimes - there is no evidence to support this.
- There is no evidence to suggest that use of emergency contraception can cause infertility.
- If you are already pregnant, emergency contraceptive pills or the coil will not work.
- Emergency contraception does not provide any protection from sexually transmitted infections after having unprotected sex.

For more information on emergency contraception visit **thinkcontraception.ie**

Your emergency contraception choices

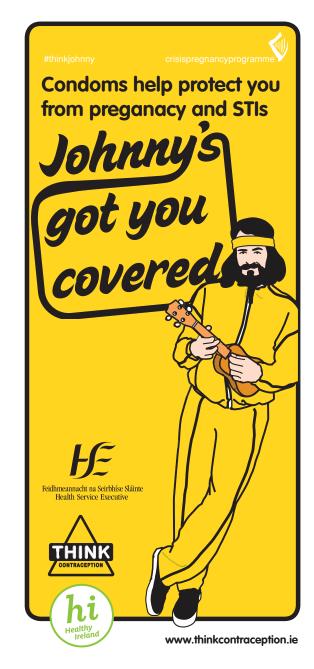
There are different emergency contraception choices for different situations, depending on when you had your last period and how long it has been since you had unprotected sex.

	3 Day Pill
	(NorLevo® or Prevenelle®)
Time limit for use after unprotected sex	72 hours (3 days)
Effectiveness	Is 99% effective in preventing pregnancy if taken within 12 hours after unprotected intercourse. It is less effective on day 2 and day 3.
	NorLevo® is available directly from pharmacists.
Available	Medical card holders require a prescription from a GP (including out of hours co-ops) or a Family Planning Clinic.
Works by	Delaying ovulation.
	After using emergency contraception, it's important to talk to a doctor or pharmacist about the following:
	what to do if you are already using regular contraception
Future protection	• when you can expect your next period
,	what to do if your period doesn't come
	a regular contraceptive option suitable for you
Cost	The cost of contraception varies depending on what form is most suitable to you, what providers are available to you and whether or not you have a medical card. Talk to a pharmacist, GP or Family Planning Clinic for more information on costs.

Emergency contraception is more effective the sooner you take it after having unprotected sex. Ask a pharmacist for a private consultation or talk to your GP or Family Planning Clinic about the best option for you. You can also use this time to discuss regular contraception. The following table will give you an outline of the choices available.

	5 Day Pill (ellaOne®)	The Copper Coil (Post Coital IUD)
	120 hours (5 days)	120 hours (5 days)
ncy ted 2 and	Is 99.5% effective but should be taken as soon as possible.	Is 99.9% effective but get advice as soon as possible.
of nic.	ellaOne® is available directly from pharmacists. Medical card holders require a prescription from a GP (including out of hours co-ops) or a Family Planning Clinic.	Can be inserted by specially trained GPs or Family Planning Clinics.
	Delaying ovulation.	Preventing sperm from joining an egg Preventing the fertilised egg from attaching to the uterus.
it's acist	After using emergency contraception it's important to talk to a doctor or pharmacist about the following: • what to do if you are already	Can be left in the uterus for up to 10 years as a regular method of contraception Or Can be removed if required at
od me	using regular contraception • when you can expect your next period	your next period
ble	 what to do if your period doesn't come 	
	 a regular contraceptive option suitable for you 	
nding nd ird. nning	The cost of contraception varies depending on what form is most suitable to you, what providers are available to you and whether or not you have a medical card. Talk to a pharmacist, GP or Family Planning Clinic for more information on costs.	The cost of contraception varies depending on what form is most suitable to you, what providers are available to you and whether or not you have a medical card. Talk to a pharmacist, GP or Family Planning Clinic for more information on costs.





Free public STI screening services Carlow STI Clinic... .051 842646 Clare STI Clinic Ennis..... ..061 482382 Cork STI Clinic..... **Doneaal** Letterkenny Sexual Health Clinic (GUM).......074 9123715 GUIDE Clinic, St. James' Hospital, Dublin......01 416 2315/6 Galway Kerry STI Clinic Tralee.......021 4966844 Limerick STI Clinic ...061 482382 Dundalk Louth County Hospital GUM.Clinic.......086 8241847 Mayo STI Clinic..... Monaghan General Hospital GUM Clinic......086 8241847 Sligo GUM Clinic..... ...071 917 0473 **Tipperary** Clonmel STI clinic.... ...061 482382 Waterford STI Clinic ..051 842646 Westmeath Mullingar Midland Regional Hospital......086 4169830 **Unplanned pregnancy?**

Make the right choice for you

It is your right to decide when, with whom, how and where you want to

It is your right to make your own choices.

It is your right not to engage in sexual activity.

It is your right to protect yourself from pregnancy and disease.

It is your right to enjoy yourself.

Only you can protect yourself from unplanned pregnancy and STIs, so make sure you know your stuff and look after yourself.

Facts

Fact: You can get pregnant even if it's the first time you have had sex.

Fact: A woman can get pregnant if the man comes near or around her genitals or even if he pulls out before he comes.

Fact: In 2014, a total of 12,626 cases of sexually transmitted infections (STIs) were notified in Ireland (adapted from HPSC, 2014).

Fact: The most frequently reported STIs were chlamydia, genital warts, gonorrhoea and genital herpes (adapted from HPSC, 2014).

Fact: The majority of STIs notified were among those aged less than 25 vears and men who have sex with men (MSM) (adapted from HPSC, 2014).

Sexually transmitted infections (STIs)

Condoms offer protection against most STIs, but only total abstinence from all sexual contact offers 100% protection from pregnancy and

Get advice from your doctor, a family planning clinic or an STI clinic if you are worried about STIs or are sexually active and notice any of the following symptoms:

- unusual discharge from penis or vagina,
- pain when passing urine,
- unusual sores or blisters in the genital area,
- itching or irritation in the genital area, or
- pain during sex.

Once diagnosed, most STIs (except for HIV) can be cured with treatment. But make sure you get treatment early, as some infections can have long-

Freetext the word 'list' to 50444 or

visit **positiveoptions.ie** for a list of free support services.

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at www.emitoolkit.ie

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Am I at risk of an infection?

Following an assessment and depending on your type of sexual exposure, you may be at risk of getting some sexually transmitted infections, for example, chlamydia, syphilis and gonorrhoea. You may also be at risk for bloodborne viruses, such as: hepatitis B, hepatitis C and HIV.

How do I know if I have one of these infections?

With your consent, a blood sample may be taken in the Emergency Department to test for bloodborne viruses (hepatitis B, hepatitis C and HIV) and syphilis to rule out any infection you may already have. Arrangements will then be made for you to have blood tests carried out again over the next few months in case you have become infected as a result of this sexual exposure. You will then be referred for follow-up to the nearest Sexually Transmitted Infection (STI)/ Genitourinary Medicine (GUM) or Infectious Disease (ID) Clinic where you will be tested for other sexually transmitted infections.

If you have been sexually assaulted and it has been reported to the Gardai, you will be referred to the nearest Sexual Assault Treatment Unit (SATU) for treatment.

What treatments are available for these infections?

If you have not previously been vaccinated for hepatitis B, you may be advised to get vaccinated against hepatitis B.

- The first dose of the vaccine may be given to you in the emergency department or SATU.
- You will be told where to get the following doses which may be with your GP.
- You will be given a hepatitis B vaccination card which will outline when you should get the next doses of the vaccine.

HIV Post Exposure Prophylaxis (PEP): This is only recommended for a small number of patients and depends on the risk of HIV transmission as a result of your sexual exposure. The doctor will advise you if this treatment is required and provide you with more information about what the treatment is.

What other follow-up do I need?

- If you are being referred to a specialist clinic, you will either be given their contact details or given instructions with regard to appointments.
- A referral letter will be sent to the specialist clinic explaining the assessment and treatment that you have received.
- If you have any concerns regarding this advice or wish to receive counselling, please discuss this with your doctor.

Where will I be attending for my next appointment (including contact details?)

When is this appointment?



I am worried about pregnancy?

An emergency contraceptive or 'morning after pill' may be prescribed for you following a pregnancy test. If you are going to take the 'morning after pill', an information leaflet will be given to you which will describe what it is and how it works.



Am I allowed to be a blood donor?

You should avoid donating blood or other body fluids for the duration of your follow up.

A downloadable version of this brochure

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be

found at www.emitoolkit.ie



Referral letter to Infectious Disease/HIV Physician

Private and Confidential		
Date:		
Dear Dr. ,		
Re: Name; Address		
DOB:		
Re: Follow-up for Significant Blood /Body Fluid Exposure		
The above named person was involved in a reported blood and/or body fluid exposure incident on and attended at this service on		
This person was the: Source/Recipient of the injury (delete as appropriate).		
Relevant patient clinical information attached (tick box as appropriate):		
\Box If Recipient - copy of the patient management form detailing the assessment and management of the recipient at this service.		
☐ If Source - copy of the source individual's blood test reports.		
In addition, I wish to confirm the following (tick box as appropriate):		
□ Patient's GP informed □ Infectious diseases notification to Director of Public Health/MOH completed □ Other		
Please do not hesitate to contact this service should you have further queries or concerns.		
Yours sincerely,		

A downloadable version of this brochure can be found at www.emitoolkit.ie



Referral letter to GP or Occupational Health Department

Private	and Confidential
Date:	
Dear Dr	
Re: <i>Nan</i>	ne; Address
DOB:	
Re:	Follow-up for Blood /Body Fluid Exposure incident
fluid exp	ove named patient/employee of your organisation was involved in a reported blood and/or body cosure incident on and attended at this service on This person was the t of the injury.
	osure incident was considered to be: ignificant
□ Signi	ficant
	find attached a copy of the patient management form detailing their assessment and ement at this service.
□ comp	up required - plete the course of hepatitis B vaccination and test for hepatitis B surface antibody 8 weeks after pletion of the course of vaccination.
□ carry	out a hepatitis B surface antibody test 8 weeks from today's date.
□ wour	nd dressing.
	rion, I wish to confirm the following – red to Infectious Disease Service at
☐ Infect	tious Diseases notification to Director of Public Health completed
□ Othe	r
	ou for your cooperation in this matter and do not hesitate to contact this service should you have ries or concerns.
Yours si	ncerely,

A downloadable version of this letter can be found at www.emitoolkit.ie



Useful contact information

Consultants in Infectious Diseases/Genitourinary Medicine

Position currently vacant University Hospital Limerick

Tel: 061 301111

Dr Catherine Fleming

Dr Helen Tuite

University College Hospital

Newcastle

Galway

Tel: 091 544 544

Professor Mary Horgan

Dr Arthur Jackson

Dr Corinna Sadlier

Cork University Hospital

Wilton

Co Cork

Tel: 021 454 6400

Dr Susie Clarke

Dr Fiona Lyons

Prof Colm Bergin

Prof Fiona Mulcahy

Dr Jenny Kieran

Dr Ceppie Merry

St James's Hospital GUIDE Dept

James's St

Dublin 8

Tel: 01 416 2315/6, 01 416 2590, 01 416 2507,

01 416 2402, 01 410 3538

Fax: 01 410 3416

Dr Jack Lambert

Dr Paddy Mallon

Dr Gerard Sheehan

Dr Aoife Cotter

Mater Misericordiae University Hospital,

Eccles Street,

Dublin 7

Tel: 01 803 2000

Professor Sam McConkey

Dr Cora McNally

Beaumont Hospital

Dublin 9

Tel: 809 3000

Dr Eoin Feeney

St. Vincent's University Hospital

Elm Park

Merrion Rd.

Dublin 4

Tel: 01 221 3363/6029

Paediatric Infectious Diseases

Professor Karina Butler

Our Lady's Children's Hospital

Crumlin

Dublin 12

Tel: 4096100

Dr Paddy Gavin

Children's University Hospital

Temple Street

Dublin 1

Tel: 8784200

Health and Safety Authority

The Metropolitan Building James Joyce Street

Dublin 1

Tel: 1890 289 389

National Virus Reference Lab

UCD National Virus Reference

Laboratory

University College Dublin

Belfield

Dublin 4

Tel: 01 716 4401

Sexually Transmitted Infection/Genitourinary Medicine Clinics

Youth Health Service,

Penrose House,

Penrose Quay,

Cork City.

Tel: 076 108 4150

GMHS,

Baggot Street Clinic,

18 Upper Baggot St.,

Dublin 4.

Tel: 01 669 9553

GUIDE Clinic,

St James's Hospital,

James's Street,

Dublin 8.

Tel: 01 416 2315/6

Mater Hospital,

Eccles Street,

Dublin 7.

Tel: 018032063

Louth County Hospital,

Dublin Road,

Dundalk.

Tel: 086 824 1847

Waterford Regional Hospital,

STI clinic,

Waterford.

Tel: 051 842 646

South Tipperary General Hospital,

Clonmel,

Co Tipperary.

Tel: 051 842 646

Carlow District Hospital,

STI clinic,

Athy Road,

Carlow.

Tel: 051 842 646



Sexually Transmitted Infection/Genitourinary Medicine Clinics (Continued)

South Infirmary Victoria University Hospital,

GUM clinic,

Old Blackrock Road,

Cork.

Tel: 021 496 6844

Regional Hospital,

Tralee,

Co Kerry.

Tel: 021 496 6844

Mid Western Regional Hospital,

STI clinic,

Dooradoyle,

Limerick.

Tel: 061 482 382

General Hospital,

Nenagh,

Co Tipperary.

Tel: 061 482 382

Ennis General Hospital,

Ennis,

Co Clare.

Tel: 061 482 382

Mayo General Hospital,

Castlebar,

Co Mayo.

Tel: 094 902 1733 (Extn 3501)

University Hospital Galway,

Newcastle Rd.,

Galway.

Tel: 091 525 200

Portiuncula Hospital,

Ballinasloe,

Co Galway.

Tel: 090 964 8372 (Extn 676)

Sligo General Hospital,

The Mall.

Sligo.

Tel: 071 917 0473

Letterkenny General Hospital,

GUM/STI Clinic,

Letterkenny,

Co Donegal.

Tel: 074 912 3715

St Fintans Hospital,

Dublin Road,

Portlaoise.

Tel: 086 859 1273

Monaghan General Hospital,

Monaghan,

Co Monaghan.

Tel: 086 824 1847

Sexual Assault Treatment Units (SATUs)

Dublin

Rotunda Hospital,

Parnell Square,

Dublin 1

01 817 1736 SATU@rotunda.ie

Out of hours:

Phone hospital 01 817 1700 ask for SATU

Waterford

Waterford Regional Hospital,

Dunmore Road,

Waterford

051 842 157 wrh.satu@hse.ie

Out of hours:

Phone Hospital 051 848 000 Nurse Manager on duty

for hospital

Cork

South Infirmary Victoria University Hospital (SIVUH) Old Blackrock Rd.,

Cork.

021 492 6297

satu@sivuh.ie

Out of hours:

Phone Hospital 021 492 6100 Nurse Manager on duty

for hospital

Mullingar

Midland Regional Hospital,

Mullingar,

Co. Westmeath

044 939 4239 /086 040 9952

satu.mrhm@hse.ie

Out of hours:

Phone Hospital 044 934 0221 Nurse Manager on

duty for Hospital

Galway

Hazelwood House,

Parkmore Rd.,

Galway

091 765 751 / 087 633 8118

satugalway. hsewest@hse.ie

Out of hours:

Phone 091 757 631 Nurse Manager on duty for Merlin

Park Hospital

Donegal

Letterkenny General Hospital

NoWDOC Premises,

Oldtown,

Letterkenny,

Co. Donegal

074 9104436 Bleep 777

087 066 4593 /087 068 1964

satu.letterkenny@hse.ie

Out of hours:

Phone Hospital 074 912 5888 Nurse Manager on duty

in the Emergency Dept



Departments of Public Health

HSE East

Dr Steeven's Hospital Dublin 8 Tel: 01 635 2145

HSE Midlands

Area Office, Arden Road, Tullamore Co. Offaly Tel: 057 935 9891

HSE North-East

Railway Street, Navan, Co Meath Tel: 046 907 6412

HSE West

Finance Building, Merlin Park, Galway Tel: 091 775 200

HSE North-West

Iona House, Upper Main Street, Ballyshannon, Co. Donegal Tel: 071 985 2900

HSE South

Floor 2, Block 8, St Finbarr's Hospital, Douglas Road Cork Tel: 021 492 7601

HSE South-East

HSE Offices, Lacken, Dublin Road, Kilkenny Tel: 056 778 4124

HSE Mid-West

Mount Kennett House, Henry Street, Limerick Tel: 061 483 337

Sexual Assault Treatment Units (SATUs) (Continued)

Limerick

University Hospital Limerick, St. Nessan's Rd., Dooradoyle, Limerick Out of hours service only:

Contact shannondoc: 1850 212 999

During office hours contact Galway or Cork SATU.







Health Protection Surveillance Centre