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

December 2024

Version 1.1

HSE Public Health: National Health Protection Office

Version History		
		Version 1.1
Title of Guideline:		Guidelines for the Emergency Management of Injuries and Post-Exposure Prophylaxis (PEP)
Approved by:		Director of National Health Protection
Version Number:		1.1
Publication Date:		2 <sup>nd</sup> December 2024
Scheduled Review Date:		3 <sup>rd</sup> December 2027
Electronic Location:		https://www.hpsc.ie/a-z/emi/
Version	Final Approval Date by DNHP	List section numbers changed
Version 1.0	04/03/2024	Full guideline update.
Version 1.1	28/11/2024	<ul> <li>Updated flow-chart for management of injuries</li> <li>Updated and reinstated Patient Management Form</li> <li>Removal of antibiotic prescribing table Appendix 2. Replaced with link to antibioticprescribing.ie.</li> <li>Removal of table 'Interpretation of HBV results' and redirection to NIAC guidelines.         <ul> <li>Table numbering updated throughout.</li> </ul> </li> <li>Updated Hepatitis B Post-exposure prophylaxis table and removed 'under review' notice.</li> </ul>

#### **Summary of Guideline Recommendations**

#### Recommendations relating to Human Immunodeficiency Virus (HIV) exposures

#### HIV PEP is recommended in the following instances:

Exposure type	Recommendation	<b>GRADE</b> <sup>1</sup>
Occupational exposures	Please see the <u>needlestick exposures</u> and <u>mucosal splash exposures</u> algorithms. Human Immunodeficiency Virus (HIV) Post Exposure Prophylaxis (PEP) is <b>recommended</b> following a <b>high-risk occupational exposure</b> (sharps or mucosal splash) if the index case is known to be living with HIV and is not on antiretroviral therapy (ART) for at least 6 months, with a suppressed viral load within the last 6 months. Please see also table 6 <i>HIV PEP recommendations by type of exposure and source</i> <u>status.</u>	1C
Sexual exposures	<ul> <li>Please see the <u>sexual exposures</u> algorithm.</li> <li>HIV PEP is <b>recommended</b> following sexual exposure where there is a significant risk of HIV transmission.</li> <li>For HIV PEP recommendations by type of exposure and source status, please see <u>table 6 HIV PEP recommendations by type of exposure and source status</u>.</li> </ul>	1C
Shared Injecting Paraphernalia	HIV PEP is <b>recommended</b> for people who inject drugs (PWID) (including gbMSM who inject ("slam") "Chems" <sup>2</sup> ) after sharing needles/equipment if their index injecting partner is living with HIV AND has NOT been on ART for at least 6 months, with an undetectable plasma HIV viral load (at the time of last measurement and within the last 6 months) AND with good reported adherence	1C

#### HIV PEP is generally not recommended in the following instances:

Exposure type	Recommendation	GRADE
Occupational exposures	Please see the <u>needlestick exposures</u> and <u>mucosal splash exposures</u> algorithms.	1C
	HIV PEP is <b>generally NOT recommended</b> following a <b>sharp or mucosal splash exposure</b> if the index case is untested AND considered part of a group with higher HIV prevalence than the general population (e.g.	

<sup>&</sup>lt;sup>1</sup> See <u>Section 8: Methods</u> for further information on levels and grading of evidence.

 $<sup>^{2}</sup>$  Gay, bisexual and other men who have sex with men (gbMSM) should be specifically asked about chemsex and injecting drug use.

	gay, bisexual, and other men who have sex with men (gbMSM) or people who inject with drugs (PWID), unless there were other factors that increased likelihood of transmission (e.g. a deep exposure or blood bolus injected or a sharps exposure from a PWID particularly in the context of a local outbreak). Please see also <u>table 6 HIV PEP</u> recommendations by type of exposure and source status.	
Human bite	<ul> <li>HIV PEP is generally NOT recommended following a human bite.</li> <li>HIV PEP should only be prescribed where <u>all four</u> of the following criteria are met:</li> <li>1. It is within 72 hours of the exposure</li> </ul>	2D
	<ol> <li>There was deep tissue exposure</li> <li>The biter was, with complete certainty, bleeding from their mouth prior to the bite</li> <li>The biter is known or suspected to have a detectable HIV viral load.</li> <li>If <u>all four</u> criteria are met, HIV PEP is indicated. Outside of this, HIV PEP should not be prescribed without discussion with a physician specialising in HIV, where it may be considered in rare extreme cases.</li> </ol>	
Shared Injecting Paraphernalia	HIV PEP is <b>generally NOT recommended</b> in PWID after sharing needles/equipment with an injecting partner of unknown HIV status from a group with higher HIV prevalence than the general population, but HIV PEP can be considered on a case-by-case basis.	2D

#### HIV PEP is <u>NOT recommended</u> in the following instances:

Exposure type	Recommendation	GRADE
Occupational exposures	HIV PEP is <b>NOT recommended</b> following a <b>sharps exposure</b> if the index case is known to be living with HIV AND has been on ART for at least 6 months with an undetectable HIV viral load (at the time of last measurement and within the previous 6 months) AND reported good adherence, <u>table 6 HIV PEP recommendations by type of exposure and</u> <u>source status</u> . However due to a lack of direct evidence, a case by case decision can be made depending on the nature of the exposure.	
	HIV PEP is <b>NOT recommended</b> following a <b>mucosal splash exposure</b> if the index case is known to be living with HIV AND has been on ART for at least 6 months with an undetectable plasma HIV viral load (at the time of last measurement and within the last 6 months) AND with good reported adherence.	1C

	HIV PEP is <b>NOT recommended</b> where there is no or negligible risk of HIV transmission (e.g. through intact skin that comes into contact with HIV infected blood or other bodily fluids).	10
	exposure if the index case is untested but from a low risk group (see table 6 HIV PEP recommendations by type of exposure and source status.)	10
Sexual exposures	<ul> <li>HIV PEP is <b>NOT recommended</b> if the index partner has been on ART for at least 6 months with an undetectable plasma HIV viral load (at the time of last measurement and within the last 6 months) AND with good reported adherence.</li> <li>For HIV PEP recommendations by type of exposure and source status, please see table 6 HIV PEP recommendations by type of exposure and source status.</li> </ul>	1A
Needlestick exposure from a discarded needle in the community	HIV PEP is <b>NOT recommended</b> following a needlestick exposure from a discarded needle in the community.	2D

## Recommendations relating to Hepatitis B virus (HBV), Hepatitis C virus (HCV) and Tetanus exposures

Hepatitis B	Current recommendations relating to vaccination for HBV post-exposure prophylaxis can be found in Section 9.7 of <u>Chapter 9</u> of the NIAC guidelines. If HBIG is required, it should ideally be given within 48 hours of exposure, but not later than one week after exposure.
Hepatitis C	<ul> <li>There is no recommended post-exposure prophylaxis for Hepatitis C Virus (HCV).</li> <li>[126] Treatment of early HCV infection has been shown to be highly effective in achieving cure.</li> <li>HCV Ag or HCV RNA test should be carried out on the recipient at six weeks, 12 weeks and six months after the exposure incident</li> </ul>
Tetanus	<ul> <li>Tetanus Immunoglobulin (TIG) is recommended as post-exposure prophylaxis for those with tetanus prone wounds who meet the following criteria:</li> <li>Not adequately vaccinated or immunisation status not known (please see <u>Chapter 21</u> of the NIAC Guidelines).</li> <li>Are immunocompromised, even if fully immunised.</li> </ul>

For current recommendations regarding immunisation for tetanus post-exposure
prophylaxis, please see Chapter 21 of the NIAC Guidelines. If both TIG plus a vaccine
are to be given, administer at separate sites.

#### **List of Algorithms**

- Management of Infection Risk from a Blood Borne Virus (BBV) following a needlestick or sharps injury in an Occupational or Community setting
- Management of Infection Risk following exposure of mucous membrane or non-intact skin to a Blood Borne Virus (BBV) in an occupational setting
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#### Other resources

- Flowchart for the management of injuries where there is risk of bloodborne virus (BBV)
   transmission
- Patient Management Form (in <u>Word fillable format</u> and in <u>printable PDF format</u>)

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#### 1 How to use this guideline

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).

The terms "recipient" and "source" will be used throughout these guidelines:

**Recipient**: the person who sustains the exposure.

**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.

The format of the EMI guidelines and how these are presented online has been changed in this iteration. Users of this guideline should refer to the summary of recommendations for quick access to decision-making tools. Direct links to the algorithms and tables also are provided on the HPSC website.

These guidelines were produced in conjunction with an expert Guideline Development Group (GDG) and have been approved for publication by the Chairperson of this group, and by the Director for National Health Protection. Please see <u>Appendix 9</u> for details on membership of the GDG.

#### **Recommendation labels**

Recommendation labels were applied to the HIV PEP recommendations adopted and/or adapted from BASHH only.

In this version of the EMI guideline, each of the HIV PEP recommendations are colour-coded according to the direction of the recommendation: Recommended (green), not recommended (red), or generally not recommended (orange). A code is also included next to each HIV PEP recommendation, which reflects the level and grading of the evidence informing the recommendation. An explanation of these codes can be found in <u>Section 8: Methods</u>.

#### Section under review at the time of publication

The following section remains under review at the time of publication:

• If the source is unknown or known but declines testing, Page 15. The content and advice contained within this section is current and applicable at the time of publication, however the section is pending review by a legal consult and therefore may be subject to change in future.

#### 1.1 Summary of changes to guidelines

#### 2024

Work on reviewing and updating the EMI guidelines began in 2022. The HIV PEP recommendations contained in this iteration of the guidelines were either adapted or adopted from the UK Guideline for the use of Post-Exposure Prophylaxis 2021 (the BASHH guidelines) [1] or from the Post-Exposure Prophylaxis (PEP) Guidelines for children and adolescents potentially exposed to blood-borne viruses (CHIVA guidelines) [2]. Treatment recommendations relating to children have been adopted from the CHIVA guidelines also. A public consultation on the HIV PEP recommendations took place in February 2023, and all relevant feedback was incorporated following discussion with the GDG.

Minor revisions to indications for baseline and follow-up testing were adapted from the BASHH guidelines [1].

Recommendations in relation to Hepatitis B, Hepatitis C and Tetanus were reviewed by the guideline development group and, where relevant, other subject matter experts, and updated based on expert consensus and current advice contained in the National Immunisation Advisory Committee (NIAC) guidelines.

#### **HIV PEP recommendations**

#### Categorisations

'Blood splash to non-intact skin' is now categorised as 'mucosal splash exposure'.

Mucosal splash exposure means contact with potentially infectious bodily fluids or tissue which pose risk of transmission of HIV through either a mucous membrane (e.g. splash exposure to the eye) or non-intact skin exposure (e.g. exposed skin that is abraded or afflicted with dermatitis). Body fluids implicated in the transmission of HIV include blood, semen and vaginal secretions but risk is lower for non-blood containing body fluids. Other body fluids that could potentially be infectious are cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids. Fluids that are not considered infectious (unless they contain visible blood) include faeces, nasal secretions, saliva, gastric secretions, sputum, sweat, tears, urine and vomit [1].

#### For source of unknown HIV status from a high prevalence country/risk group

- Receptive vaginal sex exposure changed from 'consider' to 'generally not recommended'.
- Insertive vaginal sex exposure changed from 'consider' to 'not recommended'.
- Sharing of injecting equipment exposure changed from 'consider' to 'generally not recommended'.
- Needlestick from a discarded needle in the community exposure changed from 'consider in very limited circumstances' to 'not recommended'.
- Needlestick direct from source exposure changed from 'consider' to 'generally not recommended'.
- Mucosal splash exposure (formerly blood splash to non-intact skin/eye or mouth) changed from 'not recommended' to 'generally not recommended'.

#### For source known to be living with HIV, HIV VL unknown/detectable

- Human bites exposure changed from 'consider in very limited circumstances' to 'generally not recommended'.
- Mucosal splash (formerly blood splash to non-intact skin) exposure changed from 'consider' to 'recommended'.

#### Intravenous use of sexualised drugs (chemsex)

New recommendation: Gay, bisexual and other men who have sex with men (gbMSM) should be specifically asked about chemsex and injecting drug use.

#### **Prescribing PEP**

Removal of 3–5-day starter pack. Updated to include 5 day\* Starter Pack OR 28-day Full Course Pack (according to local protocol).

\*5-day starter packs are most commonly dispensed in the Emergency Department (ED) or Sexual Assault Treatment Unit (SATU) setting. 28-day supply is usually provided in Genitourinary Medicine/Infectious Disease (GUM/ID) setting. Some EDs may, by arrangement with their local GUM/ID service give a 28-day supply following initial ED assessment.

#### <u>Hepatitis B</u>

Inserted links to Chapter 9 of the NIAC guidelines. Replaced HBV interpretation of results table with link to NIAC Table 9.6.

<u>Table 5 Baseline and follow up testing</u>: this table has been adapted from the <u>UK Guideline for the use</u> of <u>HIV Post-Exposure Prophylaxis 2021</u> and replaces Testing of recipient where a significant exposure has occurred and Baseline recipient investigations prior to prescribing PEP.

#### <u>Tetanus</u>

Removed table *Risk assessment of wounds for use of vaccination and tetanus immunoglobulin (TIG)* and linked out to Chapter 21 of the NIAC guidelines.

#### Prevalence data

The prevalence data for Ireland has been reviewed and updated. Please see <u>Appendix 1</u> for further details.

#### **Previous updates**

Minor updates to the EMI Guidelines were also published in 2014, 2016 and 2018.

#### 2 Background to the guidelines

Exposures where there is a risk of transmission of infection frequently present in emergency departments, sexual assault treatment 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 exposed persons, and the potential opportunity to avert acquisition of infection. The appropriate management of such exposures, 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 exposed person.

These guidelines are intended for use in emergency medical settings where a patient first presents with an exposure (including needlestick or other sharps exposure, sexual exposure, human bite, exposure of non-intact skin or of mucous membranes) where there is a risk of transmission of infection, in particular bloodborne viruses (BBV). These guidelines are relevant to exposures occurring to members of the public in a community setting and also to exposures sustained occupationally (such as to health and care workers (HCW) or members of An Garda Siochana).

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

#### 2.1 Purpose and scope

The purpose of these guidelines is to provide comprehensive guidance on the appropriate management of exposures 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 exposure, for example, a hospital emergency department or occupational health department, a general practice, a dental practice, 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; health and care workers (HCW) or other workers (e.g. members of An Garda Siochana or the Defence Forces) in an occupational setting; adults and children; both recipients and sources of exposures.

#### Type of exposure

Needlestick or other sharps exposure, sexual exposure, human bites, mucosal splash exposure. These guidelines do not cover exposures where the source is an animal.

#### Time

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

#### The main questions covered by the guidelines are:

- What first aid treatment should be administered?
- Is the exposure significant?
  - What materials are significant for BBV transmission?
  - What exposures are significant for BBV transmission?
- How to assess the risk of transmission of BBVs?
  - What is the level of risk of HBV, HCV or HIV?
  - What factors in the exposure 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?

### **3** Assessing the risk of infection

#### 3.1 Initial assessment

Please refer to the *flow chart for management of injuries where there is risk of bloodborne virus (BBV)* <u>transmission</u> and the <u>Patient Management Form</u>.

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

Please also refer to the relevant algorithms for the management of <u>needlestick/sharps</u>, <u>mucosal splash</u> <u>exposures</u>, <u>sexual exposures</u> and <u>human bite exposures</u>.

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

#### Urgent first aid and initial wound care

Urgent first aid treatment should be administered if required, and an urgent assessment should be made regarding the need for HIV post-exposure prophylaxis (PEP). Please refer to <u>Tables 3 HIV</u> <u>transmission risk by exposure type</u> and <u>Table 6 HIV PEP recommendations by type of exposure and</u> <u>source status</u> for more information.

#### For contaminated needlestick exposures, sharps exposures or human bites:

- Encourage the wound to bleed.
- The recipient should not suck the exposure 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.

#### 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.
- 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 exposure has broken the skin.

#### Decide if a significant exposure has occurred

For information on the risk of transmission by exposure type, please refer to <u>Table 1 Hepatitis B</u> <u>transmission risk by exposure type</u>, <u>Table 2 Hepatitis C transmission risk by exposure type</u> and <u>Table 3</u> <u>HIV transmission risk by exposure type</u>.

#### Assessment of significance of exposure

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

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

Blood, semen and vaginal secretions and other body fluids containing visible blood, represent a risk of BBV transmission if the source has a HBV, HCV and/or HIV infection and, in the case of HIV, is not on effective antiretroviral therapy [3]. Outside the body, HCV and HIV significantly decline in infectivity within a few hours. HBV can remain infectious for a week or more.

#### 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 exposure 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.

#### Other materials:

The risk of transmission of BBVs from mucosal splash or splash to non-intact skin 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.

#### Significant exposures include:

- Percutaneous exposures;
- Human bites which break the skin, i.e. involving a breach of the epidermis, not just bruising or indentation of the skin;
- Exposure of non-intact skin to blood or body fluids;
- Exposure of mucous membranes (including the eye) to blood or body fluids (e.g. by splashing); and
- Sexual exposure (condomless and PrEP-less).

#### Non-significant exposures include:

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

#### Non-significant exposure

If the incident involves exposure to a low-risk material or a non-significant exposure, no further testing or examination is required. **The patient should be reassured and discharged.** The patient should be given an <u>information leaflet</u> and a <u>discharge letter</u> 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.

#### 3.2 Risk assessment

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 a Person Living with HIV (PLWH), their most recent viral loads, duration on and adherence to ART;
- 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, sex worker (SW), gay, bisexual and other men who have sex with men (gbMSM), born in an endemic country (see <u>AIDSInfo</u> for global HIV prevalence data), 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 exposure and the type of material involved;
- The HBV vaccination status of the recipient; and
- The infectious status (HBV, HCV, HIV), if known, of the recipient.

Please see <u>Table 1 Hepatitis B transmission risk by exposure type</u>, <u>Table 2 Hepatitis C transmission risk</u> by exposure type and <u>Table 3 HIV transmission risk by exposure type</u> for more information on transmission risks.

#### 3.3 Investigation of source

Please see Checklist: Testing of source person or recipient.

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

#### 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 living with HBV, HCV or HIV.
- Ask if they have risk factors for BBVs (e.g. PWID, SW, gbMSM, born in an endemic country (see <u>AIDSInfo</u> for global HIV prevalence data) or have a 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 testing should be carried out to estimate the risk of transmission. See <u>Table 1 Hepatitis B transmission risk by exposure type</u> for more information.
- 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 known to be HIV Ag/Ab positive, determine if they are on antiretroviral therapy and the most recent HIV viral load. Many individuals will be aware of their results. Where there is any doubt about the source's viral load or adherence to treatment, contact their treating physician to ascertain these parameters.

Where the source is considered likely to be in the window period for a BBV, they should be advised to have repeat testing until the follow-up BBV testing after the appropriate window period is negative. In such situations, discuss emergency management of the recipient with a HIV/ID specialist.

Verbal 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 health services available 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. The <u>Source information leaflet – testing for hepatitis B, hepatitis C and HIV</u> should be provided. If the source refuses consent, this fact should be recorded by the health professional.

The source should be informed that the result will be provided by the testing laboratory to their nominated doctor (GP and/or consultant) and that the recipient will also be told the result, as it will have a potential impact on their health. If, as a result of the outcome of this testing, follow-up care is necessary for the source person (e.g. referral to a HIV service), this is the responsibility of the ordering physician to ensure there is a plan in place for appropriate follow-up of results, and may include follow-up with GP.

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 a HCV RNA test is required, arrangements should be made with the testing laboratory. 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 considered at higher risk of recent BBV acquisition, consider whether HIV PEP or HBV PEP (vaccine or immunoglobulin) 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.

#### 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 is verbal. Written consent is unnecessary and may be a barrier to testing.

#### If the source is unknown or known but declines testing (This section is under review)

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). Consideration on use of HIV PEP in such circumstances should be assessed in terms of nature of injury and contextual assessment of risk factors impacting on likelihood of significant exposure risk.

Where the source is considered at higher risk of recent BBV acquisition, and there is likely to be a delay in obtaining consent or results, initiation of HBV immunisation, HBIG and HIV PEP may be indicated while further information is being obtained.

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 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

#### Please see 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 (Health and care workers (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.

Verbal informed consent should be obtained and documented before testing is carried out. This information leaflet (significant exposure to bloodborne viruses) should be provided.

Request HBsAg, antibody to hepatitis B core antigen (anti-HBc), anti-HCV and HIV Ag/Ab. If the recipient is documented to have an adequate response to HBV vaccine, it is not necessary to test for HBsAg (see Table 4 *Hepatitis B post-exposure prophylaxis*.)

Follow up testing for HBV should be carried out, as per <u>Table 5 Baseline and follow up testing</u>. For interpretation of HBV test results, see NIAC guidelines <u>Chapter 9</u>, Table 9.6.

• 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 from a group with a higher prevalence of HIV than the general population, 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 recipient**

Following a significant exposure, BBV testing of the recipient at baseline and over a period of followup is indicated. Details of recommended tests are outlined in <u>Table 5 Baseline and follow up testing</u>).

If no significant exposure has occurred, then no recipient testing is required. However, individuals may wish to know their HIV, HBV and HCV status and avail of testing at this time.

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 higher risk for recent BBV acquisition, then further testing of the recipient is not required. However, individuals may wish to know their HIV, HBV and HCV status and avail of testing at this time.

Informed consent should be obtained verbally from the recipient before any testing is carried out. Baseline testing is to reflect the recipient's current status - not to test for infection related to the current exposure.

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, 12 weeks and six months after the exposure incident. 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.

#### **Anti-HBs testing**

If the recipient was previously vaccinated but anti-HBs level post-vaccination is unknown, and HBIG administration (in addition to vaccine booster) is now being considered, an anti-HBs test at baseline should be carried out urgently. If the anti-HBs is ≥10mIU/mI, HBIG is not indicated. If anti-HBs is <10mIU/mI, 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.

#### 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 exposure.

#### 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 <u>Table 5 Baseline and follow up testing</u>).
- Give the details and contact number (preferably mobile number) of the healthcare professional to whom the results should be sent.

#### **Positive test results**

If any of the test results are positive, a referral to an appropriate specialist should be made (Please see referral letter to Infectious disease/HIV physician).

#### **Testing of needles**

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

#### **4** Recommendations for HIV exposures

#### 4.1 Occupational exposures

While reviewing these recommendations for the management of HIV following an occupational exposure, it is important to also refer to <u>Table 6 HIV PEP recommendations by type of exposure and</u> <u>source status</u>, and the corresponding algorithms: <u>needlestick exposures</u>, <u>mucosal splash exposures</u>, and <u>human bites</u>.

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 healthcare facility 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 how the employee is managed which will in turn dictate the process for exposure management of the employee. The policy should come under the governance of the Healthcare Facility. Ordering clinicians are responsible for developing a system whereby test results returned from medical testing laboratories are examined and appropriate action taken in a timely manner.

In occupations where infectious exposures are recognised as potential hazards, a hierarchical approach to management is required and the focus should be on prevention [4]. 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. Where occupational exposures occur, appropriate recording of incidents should occur as per the organisation incident management system and process.

Training of employees in the correct use of instruments (including personal protective equipment) is recommended [5-8]. While this should reduce the frequency of exposures, unfortunately it will not completely eliminate blood and body fluid exposures.

The <u>needlestick/sharps exposure</u>, <u>human bite</u>, and <u>mucosal splash exposures</u> algorithms outline the initial management of any employee who is exposed to blood or body fluids in the course of their work. Local resources will dictate where the worker is managed at the initial stage (ED or other) and where follow-up is carried out (i.e. Occupational Health Department (OHD), infectious diseases

service). Health and care workers can be followed up in OHD for possible post exposure issues such as:

- Recipient interval testing.
- Fitness for Duty assessment.
- Completion of Hepatitis B vaccination course if applicable.

The risk associated with exposures to non-blood containing body fluids is thought to be lower than the risk associated with blood exposures [8]. HIV has been identified in semen, but this is significantly reduced if the index patient is on treatment and blood HIV RNA is undetectable [9]. HIV DNA has been extracted from CSF [10] and synovial fluid [11]. 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 [3]. The risk of an individual acquiring HIV following an exposure is dependent on a number of factors, including the risk that the source person is living with HIV where status is unknown, the risk that the source is living with uncontrolled HIV infection ie not on effective antiretroviral therapy and the risk of infection following a specific exposure from a person living with HIV [1]. The HPTN 052 clinical trial and the HIV Partner cohort studies have demonstrated the efficacy of suppressive antiretroviral therapy in preventing onward transmission of HIV in HIV serodifferent sexual couples, over a range of different sexual exposure types. This is summarised in <u>Table 7 Impact of Suppressive ART on HIV acquisition</u>.

If a sexual assault has occurred, the recipient should be offered referral to the nearest sexual assault treatment unit (SATU) for further management. 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, *significant exposure to bloodborne viruses* and *HIV Post-exposure Prophylaxis*).

In all cases, the details of the exposure, including the context of the exposure and the nature of the device involved, should be recorded. This information is required both in the initial assessment

process and to inform future decision making (e.g. purchasing policies, training, counselling requirements) regarding preventative measures. In addition, the healthcare facility OHD should be able to provide anonymous details of exposures to the Health & Safety Authority and for auditing purposes. No HIV infections have been reported after a CANSI [13].

The evidence informing the occupational exposures recommendations can be viewed at the evidence to decision framework <u>here</u>.

#### **Occupational exposure recommendations**

Human Immunodeficiency Virus (HIV) Post Exposure Prophylaxis (PEP) is **recommended** following a **high-risk occupational exposure** (sharps or mucosal splash) if the index case is known to be living with HIV and is not on antiretroviral therapy (ART) for at least 6 months, with a suppressed viral load within the last 6 months. Please see also <u>table 6 *HIV PEP recommendations by type of exposure* and source status. [1, 12, 14-19].</u>

#### **NOT recommended**

HIV PEP is **NOT recommended** following a **sharps exposure** if the index case is known to be living with HIV AND has been on ART for at least 6 months with an undetectable HIV viral load (at the time of last measurement and within the previous 6 months) AND reported good adherence, <u>table 6 HIV PEP recommendations by type of exposure and source status</u>. However due to a lack of direct evidence, a case by case decision can be made depending on the nature of the exposure [1].

#### **NOT recommended**

HIV PEP is **NOT recommended** following a **mucosal splash exposure** if the index case is known to be living with HIV AND has been on ART for at least 6 months with an undetectable plasma HIV viral load (at the time of last measurement and within the last 6 months) AND with good reported adherence.

HIV PEP is **NOT recommended** where there is no or negligible risk of HIV transmission (e.g. through intact skin that comes into contact with HIV infected blood or other bodily fluids) [1].

#### GRADE: 1C

GRADE: 2C

Generally NOT recommended	GRADE: 1C
Please see the <u>needlestick exposures</u> and <u>mucosal splash exposures</u> algorithms.	

HIV PEP is generally NOT recommended following a sharp or mucosal splash exposure if the index case is untested AND considered part of a group with higher HIV prevalence than the general population (e.g. gay, bisexual, and other men who have sex with men (gbMSM) or people who inject with drugs (PWID), unless there were other factors that increased likelihood of transmission (e.g. a deep exposure or blood bolus injected or a sharps exposure from a PWID particularly in the context of a local outbreak). Please see also table 6 HIV PEP recommendations by type of exposure and source status.

#### **NOT recommended**

HIV PEP is **NOT recommended** following a sharps or mucosal splash exposure if the index case is untested but from a group with lower HIV prevalence than the general population (see table 6 HIV PEP recommendations by type of exposure and source status.) [20, 21].

GRADE 1C

#### 4.2 Sexual exposures

While reviewing these recommendations for the management of HIV following an sexual exposure, it is important to also refer to <u>table 6 *HIV PEP recommendations by type of exposure and source status* and the <u>corresponding algorithm</u>.</u>

## For situations where PEP is indicated in individuals on PrEP who have missed PrEP doses please see <u>here</u>.

The risk associated with exposures to non-blood containing body fluids is thought to be lower than the risk associated with blood exposures [8]. HIV has been identified in semen, but this is reduced if the index patient is on treatment and blood HIV RNA is <400 copies/ml [9]. 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 actions outlined in the <u>sexual exposures</u> algorithm should be followed.

The evidence informing the sexual exposures recommendations can be viewed at the evidence to decision framework <u>here.</u>

#### Sexual exposure recommendations

#### Recommended

Please see the <u>sexual exposures</u> algorithm.

HIV PEP is **recommended** following sexual exposure where there is a significant risk of HIV transmission.

For HIV PEP recommendations by type of exposure and source status, please see <u>table 6 HIV PEP</u> <u>recommendations by type of exposure and source status</u>. [1, 22-34].

#### **NOT recommended**

HIV PEP is **NOT recommended** if the index partner has been on ART for at least 6 months with an undetectable plasma HIV viral load (at the time of last measurement and within the last 6 months) AND with good reported adherence.

For HIV PEP recommendations by type of exposure and source status, please see <u>table 6 HIV PEP</u> <u>recommendations by type of exposure and source status.</u>

GRADE: 1C

#### GRADE: 1A

#### 4.3 Human bite exposures

While reviewing these recommendations for the management of HIV following a human bite, it is important to also refer to <u>table 6 *HIV PEP recommendations by type of exposure and source status*</u>, and the <u>human bite algorithm</u>

#### Introduction

There have only been very few reports of HIV transmission from human bites. All cases involved deep bites where there was blood in the mouth of the biter, and where the biter had high viral loads.

The evidence informing the human bite recommendation can be viewed at the evidence to decision framework <u>here</u>.

#### Human bite exposure recommendation

Generally NOT recommended	GRADE: 2D
HIV PEP is generally NOT recommended following a human bite.	
HIV PEP <b>should only be prescribed</b> where <u>all four</u> of the following criteria are met:	
1. It is within 72 hours of the exposure	
2. There was deep tissue exposure	
3. The biter was, with complete certainty, bleeding from their mouth prior to the bite	
4. The biter is known or suspected to have a detectable HIV viral load.	
If <u>all four</u> criteria are met, HIV PEP is indicated. Outside of this, HIV PEP should not be prescribed without discussion with a physician specialising in HIV, where it may be considered in rare extreme cases. [43-51].	

#### 4.4 Needlestick exposure from a discarded needle in the community

While reviewing these recommendations for the management of HIV following a community acquired needlestick exposure, it is important to also refer to <u>table 6 *HIV PEP recommendations by type of*</u> exposure and source status, and the <u>needlestick/sharps algorithm</u>.

Exposures from discarded needles and syringes in public places create considerable anxiety regarding the possible transmission of bloodborne pathogens. While these exposures pose less of a risk than that resulting from a needlestick exposure in health-care settings, the perception of risk often results in the necessity for evaluation, testing and counselling of the exposed person [55]. Management of such exposures includes acute wound care and consideration of the need for prophylactic management, based on a detailed risk assessment. Community acquired needlestick exposures cover a wide spectrum from criminal assault with blood filled syringes to children playing with discarded syringes in public parks [53].

In contrast to the situation with needlestick exposures in health care workers, the source of blood in discarded needles is usually unknown, exposure 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 exposures are usually superficial [16].

#### **Risk of HIV transmission**

Community acquired needlestick exposures or injuries (CANSIs) are likely to carry a considerably smaller risk of HIV transmission than exposures in the occupational setting as needles found in the community have been exposed to environmental temperatures and drying for an indeterminate period of time. The risk of HIV transmission through a needlestick exposure from a discarded needle/syringe is likely to depend on several factors. These factors include the prevalence of HIV and other bloodborne viruses among PWID in the particular setting, the type of exposure sustained, the viability of the 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) [54].

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

The factors associated with increased risk are:

- the source is considered likely to have HIV
- the exposure 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

A large study in Montreal of 274 paediatric patients presenting with CANSI between 1988 and 2006 found no seroconversions [55]. HIV chemoprophylaxis was given to 39% of patients who presented after 1997. The most common site of exposure was the hand. Most of the exposures were superficial and blood was rarely visible on the needle or syringe [55].

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 [56-59].

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. 130 children received antiretroviral prophylaxis [15].

#### **Management of CANSI**

#### **Risk assessment**

Although the actual risk of infection from such an exposure 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.

The factors associated with increased risk are:

- The source is considered likely to have HIV.
- The exposure 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 exposure 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 exposure are negative, then there is no possibility of infection and no need for further testing [15]. If a significant exposure has occurred, testing the recipient for HIV, HBV and HCV should be carried out at baseline, 6 weeks and 3 months and an additional follow-up test at 6 months for HBV and HCV.

#### 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 [15].

The evidence informing the CANSI and Shared Injecting Paraphernalia recommendations can be viewed at the evidence to decision framework <u>here.</u>
# Needlestick exposure from a discarded needle in the community recommendation

#### **NOT recommended**

HIV PEP is **NOT recommended** following a needlestick exposure from a discarded needle in the community [1, 15, 52, 53, 56].

GRADE: 2D

Emergency Management of Injuries (EMI) and Post-Exposure Prophylaxis (PEP) Guidelines 2024 V1.1

### 4.5 Shared Injecting Paraphernalia

While reviewing these recommendations, it is important to also refer to <u>table 6</u> and the <u>needlestick</u> <u>exposure algorithm</u>.

The evidence informing the CANSI and Shared Injecting Paraphernalia recommendations can be viewed at the evidence to decision framework <u>here.</u>

Emergency Management of Injuries (EMI) and Post-Exposure Prophylaxis (PEP) Guidelines 2024 V1.1

#### **Shared Injecting Paraphernalia recommendations**

# <sup>3</sup> Gay, bisexual and other men who have sex with men (gbMSM) should be specifically asked about chemsex and injecting drug use.

Recommended

#### **Generally NOT recommended**

HIV PEP is **generally NOT recommended** in PWID after sharing needles/equipment with an injecting partner of unknown HIV status from a group with higher HIV prevalence than the general population, but HIV PEP can be considered on a case-by-case basis.

HIV PEP is **recommended** for people who inject drugs (PWID) (including gbMSM who inject ("slam") "Chems"<sup>3</sup>) after sharing needles/equipment if their index injecting partner is living with HIV AND has NOT been on ART for at least 6 months, with an undetectable plasma HIV viral load (at the time of last

measurement and within the last 6 months) AND with good reported adherence [14, 60-65].

#### GRADE: 1C

GRADE: GPP

# 5 Recommendations for Hepatitis B, Hepatitis C and Tetanus exposures

While reviewing these recommendations, it is important to also refer to <u>Table 4 Hepatitis B post-</u> exposure prophylaxis, <u>Table 5 Baseline and follow up testing</u>, and <u>NIAC guidelines Chapter 9</u>, Table 9.6.

#### 5.1 Hepatitis B

Up to date recommendations in relation to Hepatitis B vaccination can be found in Chapter 9 of the NIAC guidelines <u>here</u>.

#### Hepatitis B risk by exposure type

See Table 1 Hepatitis B transmission risk by exposure type,

#### Sexual exposure

HBsAg has been found in seminal fluid and vaginal secretions, although concentrations in these fluids are lower than in blood [66]. 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 other sexually transmitted infections [67].

Sexual acquisition of HBV can occur efficiently in non-immune/unvaccinated individuals) [68, 69, 70]. Risk factors for sexual acquisition among heterosexuals include having condomless and PrEP-less sex with a partner with Hepatitis B, having condomless and PrEP-less sex with multiple partners [67, 71] and those who have a prior diagnosis of HIV or syphilis [72]. Female sex workers with a history of having anal intercourse have an increased risk of HBV infection [72]. The risk of developing HBV infection is particularly high among susceptible gay, bisexual and other men who have sex with men [70,76]. Risk factors associated with sexual transmission among gbMSM include having multiple sex partners, condomless PrEP-less insertive anal intercourse and oro-anal sex ("rimming") [72, 73].

#### **Occupational exposures**

The risk of acquiring HBV from an occupational needlestick exposure when the source is hepatitis B surface antigen (HBsAg) positive ranges from 2% to 40%, depending on the source's level of viremia [74]. Those who are e antigen positive generally have higher viral loads, and the transmission rate of HBV following a needlestick exposure from a source who is e antigen positive is estimated to be between 30% and 62% [3, 8]. Similar 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 [6, 24]. 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 higher risk of HBV transmission [8].

HBV DNA has been detected in body fluids apart from blood, including saliva, urine, nasopharyngeal fluid, semen, cervicovaginal fluids and tears [75, 76, 77]. HBV transmission can occur following exposure to non-intact skin and mucous membranes. A case report describes transmission of HBV via non-intact skin, following contact with saliva and nasopharyngeal fluids from the source [78].

#### Community acquired needlestick exposure (CANSI)

The risk of transmission of BBVs following CANSIs is difficult to estimate. HBV represents the highest risk. Environmental HBV transmission is well documented and relates to its high concentration in blood and its ability to maintain infectivity on environmental surfaces [79]. HBV has been demonstrated to survive in dried blood at room temperature on environmental surfaces for at least 1 week [53]. HBV has been detected in discarded needles [74].

There are currently few reported incidents of BBV infections thought to be secondary to 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 [80]. 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 [52]. Three cases of HCV seroconversion in adults following needlestick exposures in the community have been reported [81, 82].

#### **Human Bites**

HBV has been demonstrated in the saliva of people with HBV infection and a high correlation has been shown between HBV DNA levels in serum and saliva [15, 54, 75]. Saliva has been suggested as a vehicle for horizontal transmission of HBV among non-immune 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 [76].

A literature review conducted in 2018, identified six case reports of HBV transmission following a human bite and one case report following spitting in non-immune individuals exposed. Four of these case reports occurred in learning difficulties or mental health facilities, one during a fight with a stranger and two as a result of occupational exposures (1 unvaccinated nurse, 1 policeman (vaccination status not reported)). Full genome sequencing was performed in only one case of HBV

transmission. Although rare, these low-quality historical case reports have documented transmission of HBV in the bitten non-immune person.

#### **Hepatitis B vaccine**

Vaccination against HBV is highly effective at preventing infection. Please see <u>Chapter 9</u> of the NIAC guidelines for current advice regarding the Hepatitis B vaccine.

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 <u>HBV vaccination</u> record card with the first dose entered. 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. HBIG provides short-term protection (3-6 months) and 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. 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, 12 weeks and 6 months. Where indicated, HBIG and Hep B vaccine should be administered in separate anatomic injection sites.

#### **Hepatitis B Recommendation**

Current recommendations relating to vaccination for HBV post-exposure prophylaxis can be found in Section 9.7 of <u>Chapter 9</u> of the NIAC guidelines.

If HBIG is required, it should ideally be given within 48 hours of exposure, but not later than one week after exposure.

#### 5.2 Hepatitis C

There is no recommended post-exposure prophylaxis for Hepatitis C Virus. A HCV Ag or RNA test on the recipient should be carried out at six weeks, 12 weeks and six months after the exposure incident. (See <u>Table 5 Baseline and follow-up testing</u> for more information.)

#### Transmission risks by types of exposure

See Table 2 Hepatitis C transmission risk by exposure type

#### **Needlestick exposures**

There is a wide range of reported estimates for the risk of transmission of HCV after a needlestick or sharps exposure from a source patient – between 0 and 10% [83, 84, 85]. The estimated risk from a needlestick exposure from a source with detectable HCV RNA is 6.1% [8]. The risk of developing HCV is greater after an exposure with a hollow-bore needle [84], or deep exposures [86], compared with other exposures. 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 [86]. The risk of transmission is also influenced by whether the source has a HIV co-infection (see section below).

In cold temperatures, HCV can survive in syringes for many days in laboratory studies [82]. The clinical implications of this are unknown, but the risk of acquiring HCV from an abandoned syringe depends on the prevalence of HCV in the local community. There are case reports of HCV transmission from needlestick exposures in the community [87], but as the exact incidence of exposures in the community is not known, the risk of transmission from such exposures cannot be accurately quantified.

#### Other percutaneous exposures

The risk of acquiring HCV during an operation performed by a surgeon infect with HCV is reported to be between 0 and 3.7% [88-90]. In general the risk of contracting HCV following an exposure from an unknown source is negligible [91]. 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 [92, 93]. 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 [93].

#### 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 [94, 95]. Also, transmission of HCV has occurred following splashes of infected blood onto non-intact skin [96]. The exact risk associated with these exposures is unknown.

#### Exposure to saliva (including exposures caused by human bites)

HCV RNA has been demonstrated in saliva [97, 98]. 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 non-intact at the time of the bite, are not known [99]. Inoculation with saliva has caused transmission of the virus in experimental studies [100, 101].

Studies in dentists indicate a low incidence of nosocomial transmission of HCV [102]. It is also thought, however, that HCV can be transmitted via sharing a toothbrush with an index case [98, 103].

#### Sexual exposures

In general, transmission of HCV via sexual contact is inefficient in monogamous heterosexual serodifferent couples [104]. 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 [104-106]. Higher prevalence of anti-HCV has been observed in those with multiple sexual partners, in the absence of other risks, such as injecting drug use or receipt of blood/blood products, as further evidence of the plausibility of sexual transmission [107, 108]. If a risk is present, it is likely to be very low, and a rate of transmission per heterosexual exposure has not been calculated [109].

In several European countries as well as in the United States and Australia, HCV has unexpectedly emerged as an STI among gbMSM living with HIV. Longitudinal cohort studies have confirmed a marked increase in HCV incidence among gbMSM living with HIV, but not HIV-negative gbMSM, after the year 2000 [110]. 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 gbMSM living with HIV who were not PWID [111].

#### Exposure to other body fluids

HCV RNA has been identified in blood, saliva [97], bile [112], sweat [113], semen [114], and cervicovaginal secretions [115]. The infective potential of cervicovaginal secretions is questioned [116] but may increase during menstruation [115].

#### 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% [117] (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 [118].

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 health and care worker's hands [119].

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 [120]. 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 patients who are co-infected compared to those with only HCV infection [121].

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) [122].

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 [123].

HIV status does not seem to influence the presence of HCV in semen in men co-infected with HCV and HIV [124]. HCV RNA is detected more frequently in cervicovaginal fluid from women co-infected with HIV, than in those not infected with HIV [125], especially if HCV viremia is present, or if HIV RNA is also found in the cervicovaginal secretions.

#### **Hepatitis C Recommendation**

There is no recommended post-exposure prophylaxis for Hepatitis C Virus (HCV). [126] Treatment of early HCV infection has been shown to be highly effective in achieving cure. [126]

HCV Ag or HCV RNA test should be carried out on the recipient at six weeks, 12 weeks and six months after the exposure incident.

#### 5.3 Tetanus

Tetanus is an acute potentially fatal disease characterised by muscular rigidity and intermittent spasms. It is caused by the neurotoxin produced by the bacterium *Clostridium tetani* which grows anaerobically in a contaminated wound. The toxin is taken up by nerves and blocks inhibitory synapses.

Tetanus-prone wounds can include (as per <u>Chapter 21</u> of the NIAC Guidelines):

- Puncture type injuries acquired in a contaminated environment and therefore likely to contain tetanus spores (e.g., gardening injuries);
- Wounds containing foreign bodies;
- Compound fractures;
- Wounds or burns with systemic sepsis; and
- Some animal bites and scratches particularly if the animal has been rooting in soil or lives in an agricultural setting.

Note: this list is not exhaustive; (e.g., a wound from a discarded needle found in a park may be tetanusprone. Needlestick exposures in healthcare settings are unlikely to pose a risk of tetanus).

The above wounds would be considered high-risk tetanus prone wounds if:

- Heavily contaminated with material likely to contain tetanus spores (e.g soil, manure).
- The wound or burn contains extensive devitalised tissue, or required surgical intervention which was delayed for more than six hours, even if the contamination was not heavy.

See Table 21.2, <u>Chapter 21</u> of the NIAC guidelines for current advice on tetanus immunisation.

#### Important:

If <u>both</u> Tetanus Immunoglobulin (TIG) plus a vaccine are to be given, <u>administer at separate sites</u>. 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.

#### 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 exposure 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.

#### **Tetanus Recommendation**

Tetanus Immunoglobulin (TIG) is recommended as post-exposure prophylaxis for those with tetanus prone wounds who meet the following criteria:

- Not adequately vaccinated or immunisation status not known (please see <u>Chapter 21</u> of the NIAC Guidelines).
- Are immunocompromised, even if fully immunised.

For current recommendations regarding immunisation for tetanus post-exposure prophylaxis, please see <u>Chapter 21</u> of the NIAC Guidelines. If both TIG plus a vaccine are to be given, administer at separate sites.

# 6 Treatment of recipient following a significant exposure

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 HIV, HBV and HCV but is considered to be at higher risk of recent BBV acquisition 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.

#### 6.1 General actions to be taken following a significant exposure

- Assess the need for HIV PEP (see Recommendations for HIV exposures <u>section 4</u>, and treatment <u>section 6.2</u>).
- Offer HBV vaccination unless known to be immune. See <u>Chapter 9</u> of the NIAC guidelines for information on when to offer the Hepatitis B vaccine.
- Consider HBIG (please see <u>Table 4 Hepatitis B post-exposure prophylaxis</u>).
- If applicable, take bloods for baseline testing, see <u>Table 5 Baseline and follow-up testing</u>.
- Advise no condomless, PrEP-less sex until results of final bloods following appropriate window period are available.
- If sexual exposure, in addition to the above actions: (see also <u>sexual exposures algorithm</u>):
  - Consider emergency contraception and give information leaflet.
  - 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 on sexual exposure.
  - Refer to sexually transmitted infection (STI)/GUM clinic in 2 weeks' time (see referral letter to physician specialising in HIV <u>here</u>).

The following sections outline additional actions, and information on post-exposure prophylaxis, which should be considered when the source is infected or potentially infected with a BBV.

### 6.2 HIV PEP

#### **Key points**

- 1. Only consider HIV PEP if within 72 hours of exposure [20]. PEP should not be offered if more than 72 hours has elapsed since the exposure.
- 2. Where HIV PEP is indicated, the first dose of HIV PEP should be given as soon as possible within 2 hours if possible.
- Assess risk based on type of exposure and what is known about source in line with the appropriate exposure algorithm. <u>Needle stick/sharps</u>, <u>Mucosal splash exposures</u>, <u>Sexual</u> <u>exposures</u>, <u>Human bite exposures</u>.
- 4. Where the source BBV status is not known, test for BBV where feasible.
- 5. PEP should be discontinued immediately if a HIV test on the source is found to be negative, unless the source is considered to be at higher risk of recent infection (i.e. within the HIV window period) in which case, continuation of PEP should only be on the explicit advice of a HIV physician)
- 6. There are circumstances when people who miss doses of HIV PrEP need PEP. Please see <u>here</u> for further information.
- 7. A positive pregnancy test does not preclude the use of HIV PEP.
- 8. Discuss with senior doctor in emergency medicine or HIV specialist if unsure how to proceed.

#### If PEP indicated:

- Counsel
- For all exposures: record baseline tests including
  - Creatinine (and eGFR);
  - Alanine transaminase;
  - HIV-1 Ag/Ab; and
  - If not known to be vaccinated with documented HepBsAb >10 IU: Hepatitis B serology (HepBsAg, HepBsAb, HepBcAb).
  - A pregnancy test should be done for all people of childbearing potential considering PEP.

**For sexual exposure:** as for 'all exposures', plus syphilis testing. Hep C screening in gbMSM and others at risk of hepatitis C. Where feasible chlamydia and gonorrhoea testing.

For occupational exposure: as for 'all exposures' plus hepatitis C screening in all.

- Prescribe 5-day starter pack or 28-day full course pack (according to local protocol)
- Arrange follow up at ID or GUM clinic before starter pack runs out
- Advise no condomless, PrEP-less sex until results of final bloods following appropriate window period are available

#### **Risk assessment**

The risk of an individual acquiring HIV following an exposure is dependent on a number of factors, including the risk that the source person is living with HIV where status is unknown, the risk that the source is living with uncontrolled HIV infection ie not on effective antiretroviral therapy and the risk of infection following a specific exposure from a person living with HIV [1]. The HPTN 052 clinical trial and the HIV Partner cohort studies have demonstrated the efficacy of suppressive antiretroviral therapy in preventing onward transmission of HIV in HIV serodifferent sexual couples, over a range of different sexual exposure types. This is summarised in <u>Table 7 Impact of Suppressive ART on HIV</u> acquisition.

Please see <u>Table 8 Risk of HIV transmission per exposure where source is known to be living with HIV</u> <u>and not on ART</u> (Adapted from BASHH UK Guideline for use of HIV PEPSE 2021 – source references omitted from table).

Risk of HIV transmission = risk that source is living with HIV and not on effective ART x risk of exposure (including co-factors such as sexually transmitted infections, high HIV viral load and bleeding) [1].

Please see also <u>Table 9 Estimated risk of HIV transmission by type of exposure where source HIV status</u> <u>is unknown</u>. This table 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).

For HIV PEP recommendations by type of exposure and source status, see <u>Table 6</u> (Adapted from BASHH, BHIVA, 2021 [1]).

#### Estimating probability that source is a person living with HIV

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) (see <u>checklist</u> and <u>source information</u> <u>leaflet</u>).

- The source is considered HIV negative if there is a negative 4<sup>th</sup> generation combined antibody/antigen HIV test result within the past 45 days plus no clinical indication of a seroconversion like illness since the last HIV test and source is not considered to be at higher risk of recently acquired infection.
- The source is considered to be a person living with HIV if they have a positive HIV result, or a physician has diagnosed HIV or the source self-reports a diagnosis of HIV. PEP should be discussed with the treating HIV team if the source is not on antiretroviral therapy or there are any concerns about adherence to treatment. If not contactable, commence standard PEP.
- Where the source has been confirmed to be on effective antiretroviral therapy with an undetectable HIV viral load within the last 6 months, and adherent to therapy, PEP it not recommended.

**If the exposure involves a source person with either of unknown HIV status or unknown identity** it is not possible to give reassurance that the risk of HIV infection is zero. However, it is possible to estimate risk, which is reflected in the recommendations, tables and algorithms.

#### Discussion

If the risk of HIV is estimated to be high and PEP is being considered, the risks and benefits of PEP should be discussed through shared decision making with the recipient.

#### Shared decision making regarding PEP should include discussing:

- The recommended actions as per national guidelines;
- The window period;
- The estimated risk of HIV transmission per exposure from a <u>known person living with HIV</u> and not on ART:
  - 1:1000 for receptive vaginal intercourse
  - 1:666 for insertive anal intercourse
  - 1:90 for receptive anal intercourse;
- The effectiveness, course of action and side effects of taking PEP:
  - PEP is likely highly effective but uncertainty exists
  - Take daily for 28 days
  - Side effects unusual but include: GI, rash, rarely hepatitis
  - Avoid antacids/multivitamins/Iron supplements
  - Seek help if symptoms of HIV seroconversion;
- Condoms for sex until post-window period HIV test (minimum 45 days post PEP completion).

Give the recipient an information leaflet about significant exposures.

#### 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 (see <u>referral letter</u>).

#### **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, unless there are local arrangements in place for provision of the full treatment pack; and
- Follow-up plan.

Give the recipient a <u>HIV PEP information leaflet</u>.

#### Baseline investigations of recipient prior to prescribing HIV PEP

Baseline investigations prior to prescribing PEP are outlined in <u>Table 5 Baseline and follow up testing</u>. Blood samples should be labelled "Possible BBV exposure – recipient".

#### **Prescribing HIV PEP**

Antiretrovirals are unlicensed in Ireland for PEP but are widely used internationally and accepted as best practice.

#### **Recommended adult combination:**

Tenofovir disoproxil 245mg/emtricitabine 200mg one tablet once daily PLUS Raltegravir 400mg TWICE daily

#### <u>Alternatives:</u>

- Tenofovir disoproxil fumarate 245mg/emtricitabine 200mg one tablet once daily PLUS Raltegravir 1200mg ONCE daily (note: not available as starter pack, not for use in pregnancy).
- Tenofovir disoproxil fumarate 245mg, emtricitabine 200mg one tablet once daily PLUS Dolutegravir 50mg once daily.

Where there are concerns for antiretroviral resistance in the source, or the recipient has significant renal impairment, discuss urgently with a HIV physician.

#### **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.

**<u>Tenofovir disoproxil fumarate/Emtricitabine:</u>** There are no significant drug-drug interactions anticipated with these agents and other medication.

**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.

For information on drug-drug interactions please see:

- <u>https://www.hiv-druginteractions.org/</u>
- https://www.medicines.ie/
- The British National Formulary
- The product insert for the drug

#### **Medications - adults**

#### <u>5 day\* Starter Pack OR 28-day Full Course Pack (according to local protocol):</u>

\*5 day starter packs are mostly given in the ED or SATU setting. A 28 day supply is usually provided in GUM/ID setting. Some ED's may, by arrangement with their local GUM/ID service give a 28 day supply following initial ED assessment.

Tenofovir disoproxil fumarate/Emtricitabine one tablet daily, plus Raltegravir 400mg 1 tablet twice daily, a total of 3 tablets/day.

#### Standard regimen

Tenofovir disoproxil fumarate/Emtricitabine should be taken with food as this improves tenofovir absorption and may reduce nausea. If patients have difficulty in swallowing, tenofovir disoproxil fumarate/emtricitabine can be dispersed in approximately 100ml of water or orange juice and taken immediately. Raltegravir tablets should be swallowed whole and not chewed, broken or crushed (www.medicines.ie).

All patients should be reviewed by 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 (<u>PEP information leaflet</u>).

#### **Potential Side Effects**

Tenofovir disoproxil fumarate/Emtricitabine and Raltegravir: 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. Further information on dosing and potential side effects and drug-drug interactions can be found in the relevant summary of product characteristics (http://www.medicines.ie/).

#### **Special Prescribing situations**

- Source is known to be living with HIV and on antiretroviral drugs but without an undetectable viral load for 6 months: Discuss with the physician specialising in HIV. If not contactable, commence standard starter pack and ensure follow up with physician specialising in HIV urgently.
- 2. Where known pre-existing renal impairment: Give first dose of Tenofovir disoproxil fumarate/Emtricitabine and Raltegravir: and discuss with physician specialising in HIV regarding the need for dose adjustment.
- 3. Pregnancy: If indicated, commence same PEP. Ensure urgent specialist follow up.
- 4. Breastfeeding: Where there is a clear recommendation for PEP in someone who is breastfeeding or someone who is planning to breastfeed, discuss the case with adult and paediatric specialists recognising the time sensitive window for PEP initiation.

#### 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 (please see referral letter to physician specialising in HIV <u>here</u>). Note: Starter packs are not used in paediatrics. Follow-up arrangements should be recorded in the patient's notes.

#### **Medications - children**

(Adopted from Post Exposure Prophylaxis (PEP) Guidelines for children and adolescents potentially exposed to HIV, <u>CHIVA UK guidance 2021</u> [2]).

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.

- Young people from 12 years of age and over 40kg who are able to swallow tablets should receive PEP as for adults: Raltegravir 400mg 1 tablet twice daily + Tenofovir disoproxil fumarate/emtricitabine 1 tablet daily.
- Young people 12 years of age or older with renal insufficiency should not receive Tenofovir and should therefore be given: Raltegravir 400mg 1 tablet twice daily + fixed dose combination of Lamivudine 150mg/Zidovudine 300mg 1 tablet twice daily.
- 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. Lopinavir/ritonavir 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.

*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.

The recommended regimen should be selected using <u>Table 10 Suggested Paediatric PEP regimens</u> [2]. <u>Table 11 HIV PEP Drugs, Doses and Side effects</u> provides guidance on dosing and adverse events but individual dosing for children <40kg should be discussed with the Infectious Diseases consultant on call at Children's Health Ireland by phone. Please see <u>Table 8 Risk of HIV transmission per exposure</u> where source is known to be living with HIV and not on ART, <u>Table 10 Suggested Paediatric PEP</u> regimens and <u>Table 11 HIV PEP Drugs, Doses and Side effects</u>.

Dosing is correct as per date of guideline publication but for updated dosing see CHIVA ART dosing table <u>here</u>. Generally, medicines are well tolerated with the exception of minor, initial gastrointestinal disturbance and possible headache.

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.

#### 6.3 Hepatitis B

In situations where HBIG is indicated (please see <u>Table 4 Hepatitis B post-exposure prophylaxis</u>), 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<sup>®</sup> (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<sup>®</sup> 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<sup>®</sup> or mix Hepatect CP<sup>®</sup> 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® <u>Summary of Product Characteristics (SPC)</u>:

"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<sup>®</sup> 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.

#### 6.4 Hepatitis C

There is no recommended post-exposure prophylaxis for HCV, however treatment of early HCV infection has been shown to be highly effective in achieving cure [126].

It is essential that patients who develop acute Hepatitis C infection are diagnosed as soon as possible to allow for early treatment. 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 also be advised to avoid PrEPless, condomless sexual contact.

#### 6.5 Tetanus

See <u>Chapter 21</u> of the NIAC guidelines for current advice regarding tetanus.

Depending on the circumstances of the exposure, tetanus immunisation should be considered.

#### 6.6 Dental and primary care exposures

#### **Exposures in primary care medical practice**

Exposures occurring in a primary care setting should be managed in a similar manner as exposures occurring within a dental practice. Where there is relevant expertise within a medical practice then it may be more appropriate to deal with the exposure and follow-up within that practice.

#### **Exposures 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 exposed person. The legislation which covers this area is the Safety, Health and Welfare at Work Act 2005 (and 2007 Regulations).

#### **Emergency management of an exposure**

1. Immediate wound hygiene should be carried out.

- If a significant exposure has occurred (i.e. a bite, or an exposure from a used needle or from a used sharp) immediate referral should take place to the appropriate unit (emergency department or infectious disease specialist) where a definitive risk assessment is carried out.
- 3. The management of the recipient (exposed 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 <u>On-Site Assessment Form</u> which is also downloadable from the IDA website (<u>www.dentist.ie</u>). 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 exposure 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.

#### 6.7 Antibiotic treatment

Prophylactic antibiotics are not routinely recommended for needlestick exposures, although each wound should be assessed individually. Antibiotic prophylaxis is indicated after human bites, especially to the hand (please <u>see algorithm on human bites</u> for further information on human bite exposures).

For information on antibiotic prescribing please see <u>here</u>. Specific information on antibiotic prescribing following a human or animal bite can be found <u>here</u>.

# 7 Information and follow-up of recipient

#### 7.1 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 (*no risk of exposure to bloodborne viruses*) and discharged.

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 (*significant exposure to bloodborne viruses*) should be given. If the recipient has particular concerns, formal counselling may be arranged.

#### **Precautions**

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

- Adopt safer sex practices (i.e. use condoms) until the follow-up BBV (and syphilis where indicated) testing after the appropriate window period is negative.
- 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 *significant exposure to bloodborne viruses*).

#### 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; and
- 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 exposure.

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 (Please see <u>HIV PEP</u> information leaflet and referral letter for ID/HIV physician).

#### For recipients not prescribed HIV PEP:

- Healthcare staff who have received an occupational exposure 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 (please see <u>referral letter</u> for GP or Occupational Health Department).
- Members of the public should be referred to their own GP and/or the local STI/ID/GUM/SATU service.

#### 7.2 Records/documentation

#### **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.

#### **Notifiable diseases**

HBV, HCV, Syphilis 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).

A notification form may be downloaded from the HPSC website here.

#### **Occupational exposure**

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

If, as a result of a work-related exposure, the employee is absent from work for more than 3 consecutive days, the employer must report the exposure 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 exposure 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 <u>www.hsa.ie</u>

#### **Risk management forms for hospital**

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

### 8 Methods

The original version of this guideline was developed in 2012. This version of the guideline was fully updated in 2016, and a further update was made in 2018 to amend Dolutegravir prescribing information in the context of pregnancy and women of childbearing potential. The working group that developed these guidelines was 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 at this time but agreed to be available for consultation during the course of the guideline development. The members of the working group and the organisations they represented are listed in the appendices of this document.

#### 8.1 Search strategy

In developing the recommendations for the 2012, 2016 and 2018 versions of these guidelines various sources of guidance were reviewed. Initially, existing guidelines for the management of needlestick exposures, 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 exposures; 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 exposure such as a human bite, extensive consultation with international oral health experts was conducted.

For the most recent HIV PEP update (2022), a comprehensive search for relevant national and international guidelines was conducted to identify specific recommendations that could be adopted or adapted in the Irish context. The Population, Interventions, Comparison and Outcome (PICO) framework guided the development of the search strategy. The initial search was performed in PubMed using a combination of controlled vocabulary and free text terms to ensure maximum retrieval. The search terms were then adapted for Medline (ProQuest) and TRIP database. The websites of key organisations were also searched. Published guidelines from 2018 were included. The Preferred Reporting Items for Systematic reviews and Meta-analysis (PRISMA) flow diagram was used for the selection of guidelines for inclusion.

From these searches, a total of 131 results were obtained. Eight records were excluded due to duplication. A total of 123 records were screened for eligibility, of which 12 met the inclusion criteria.

A team of 7 reviewers appraised the 12 included guidelines using the AGREE II (Appraisal of guidelines for research and evaluation) tool [127], with 2 reviewers appraising each guideline independently.

Following on from the application of the AGREE II instrument, five guidelines were identified as being suitable for inclusion to inform the HIV PEP guideline update.

#### 8.2 Formulation of recommendations, 2022-2024 update

A working group of the main Guideline Development Group (GDG) was established, and a virtual meeting was held on the 20th July 2022. GRADE (Grading of Recommendations, Assessment, Development and Evaluations) evidence summaries (considered judgement forms) were produced to inform the updating of the HIV PEP recommendations [128]. These considered judgement forms were populated for each of the key HIV PEP questions with recommendations from the international guidelines and Irish epidemiology data. Considering the currency and quality of the guidelines, the level of evidence supporting the recommendations, the balance of benefits and harms, resource use, acceptability, feasibility of implementation, the working group agreed to either adapt or adopt the UK Guideline for the use of HIV Post-Exposure Prophylaxis 2021 guidelines for updating the specific HIV PEP recommendations. The GRADE-adolopment framework informed this process [128]. The level of evidence described within the source guideline (i.e., UK Guideline for the use of HIV Post-Exposure Prophylaxis 2021 guidelines) was also reviewed. The final recommendations were then presented to the main GDG to consider the criteria that influenced the direction and strength of the recommendations from the source guideline. Treatment recommendations relating to children have been adopted from the Post-Exposure Prophylaxis (PEP) Guidelines for children and adolescents potentially exposed to blood-borne viruses. Minor revisions to indications for baseline and follow-up testing were adapted from the UK Guideline for the use of HIV Post-Exposure Prophylaxis 2021. Prevalence data for Hepatitis B, C and HIV was also reviewed and updated. Recommendations relating to Hepatitis B, Hepatitis C and Tetanus were reviewed by a focused working group and considered against current advice contained in the relevant chapters of the NIAC guidelines. Furthermore, the Hepatitis C sections were reviewed by the National Clinical Lead for Hepatitis C. Minor revisions to the wording of the Hepatitis C and Hepatitis B recommendations were agreed based on consensus of the working group, subject matter experts and the GDG.

**Evidence to decision** frameworks for the HIV PEP recommendations can be viewed at the following links:

- Occupational exposures
- <u>Sexual exposures</u>
- Human bite exposures

Emergency Management of Injuries (EMI) and Post-Exposure Prophylaxis (PEP) Guidelines 2024 V1.1

<u>Community-acquired needlestick injury and Shared Injecting Drug Paraphernalia</u>
<u>recommendations</u>

#### Level and grading of evidence

The HIV PEP recommendations adopted from BASHH were labelled according to the following matrix to outline the strength and certainty/quality of the evidence informing them (as per GRADE methodology).

Strength		Certainty or quality	
Strong	1	High	A
Weak	2	Moderate	В
		Low	С
		Very low	D
GPP: Good practice point.			

For example, a strong recommendation informed by high certainty or quality of evidence would be labelled 1A.

A good practice point (GPP) or good practice statement is recommended best practice based on the experience of the guideline development group.

A strong recommendation is given when there is high-certainty evidence, or lower-certainty evidence paired with consistent panel expertise, showing that the overall benefits of the intervention are clearly greater than the disadvantages. This means that all, or nearly all, patients will want the recommended intervention.

A conditional or weak recommendation is given when it is considered that the benefits of the intervention are greater than the disadvantages, or the available evidence cannot rule out a significant benefit of the intervention while assessing that the adverse effects are few or absent. This recommendation is also used when patient preferences vary.

A strong recommendation against the intervention is given when there is high-certainty evidence, or lower-certainty evidence paired with important contextual factors, showing that the overall disadvantages of the intervention are clearly greater than the benefits, or that the intervention is not effective. A strong recommendation is also used when the examination of the evidence shows that an intervention is not safe. A conditional or weak recommendation against is given against the intervention when it is judged that the intervention may not be effective, but certainty is low. This recommendation is also used where the intervention is not likely to be effective, but it may be useful in specific settings or populations. Likewise, it is also used when patient preferences vary.

# **Appendices**

#### Appendix 1 Prevalence and epidemiology of bloodborne viruses

#### **Hepatitis B virus**

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 [129].

Acute infection is clinically recognised in only a small proportion of cases; less than 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 [129].

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 [130]. Since 2008, the 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 health and care workers (HCWs), 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 [131].

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 [3]. 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 a person with HBV infection, perinatal mother to infant transmission, injecting drug use and nosocomial exposure [129].

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 exposures from contaminated sharp instruments sustained by hospital personnel [132].

The risk of an infant acquiring HBV perinatally from a mother with HBV infection is 70-90% when the mother has a high hepatitis B viral load as evidenced by the presence of HBsAg and HBeAg. The risk is 5-20% when the viral load is low, when the mother is HBsAg positive but HBeAg negative.

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

#### **Prevalence of HBV infection**

#### **Global distribution of HBV**

Hepatitis B virus prevalence is highest in Sub-Saharan Africa and East Asia, where between 5% and 10% of the adult population is chronically infected. High rates of chronic infection are also found in the Amazon region of South America and the southern parts of eastern and central Europe. An estimated 2–5% of the general population is chronically infected with HBV in the Middle East and the Indian subcontinent. Australia, New Zealand and North America have similar HBsAg prevalences to northern and north-western European countries (<1%). Mother-to-child transmission of hepatitis B virus is a major mode of transmission in high prevalence settings and Immunisation is the most effective strategy for prevention of HBV infection [133].

Please see <u>here</u> for more information on global distribution of HBV.

#### Hepatitis B infection in Europe

Thirty EU/EEA Member States reported 16,187 cases of hepatitis B virus (HBV) infection for 2021. Excluding the three countries that only reported acute cases, this corresponds to a crude notification rate of 4.7 per 100,000 population. Acute/chronic status was only reported for 50% of cases; 86% were reported as chronic infections and 14% as acute infections. The highest notification rates were in 35-44 year olds. The notification rates for acute cases have continued to decline, most likely reflecting the impact of national vaccination programmes. Where risk factor information was reported for acute cases, the most common risk factors were heterosexual sex (30%), gbMSM sex (16%) and nosocomial transmission (12%) [134].

The total percentage of people with HBV varies between different countries, with higher rates in southern, eastern and central European countries. The countries with the highest prevalence are

Romania and Bulgaria (>4%), followed by Slovenia, Greece and Lithuania (2-3%). Other European countries not considered endemic for hepatitis B, but with an estimated HBsAg prevalence of 1-1.9% are Hungary, Poland, Latvia, Croatia, Italy and Portugal. Most countries in Northern and Western Europe, including Ireland, have a low general population HBsAg prevalence (<1%) [135]. Prevention and control programmes, including comprehensive vaccination programmes, need further scaling up if European countries are to achieve the goal of eliminating hepatitis B [133, 136].

#### Ireland

The prevalence of HBV in the general population in Ireland is low. Hepatitis B has been included in the primary immunisation schedule, for children born after 1st July 2008, since October 2008, with doses given at 2,4 and 6 months as part of the 6 in 1 vaccine. However, HBV is more prevalent in certain subgroups of the population, such as migrants who were born in countries with intermediate (2-7%) or high (>8%) HBV endemicity, household contacts of cases, people who inject drugs (PWID), gay, bisexual and other men who have sex with men (gbMSM) and people with multiple sexual partners [130, 131, 137].

#### Groups at lower risk of HBV acquisition in Ireland

#### **General population**

A study using residual sera collected in 2003 estimated the HBsAg prevalence (current infection) in the general population in Ireland to be 0.1% [138]. Significant numbers of people have migrated to Ireland from HBV endemic countries since this study was carried out; therefore the prevalence of HBV infection is likely to have increased since then.

An evaluation of the hepatitis B enhanced surveillance system in Ireland was carried out in 2017. As part of this evaluation, the national HBsAg prevalence was estimated using published hepatitis B prevalence data by country of birth and census data on the population of Ireland by country of birth. The estimated HBsAg prevalence ranged from 0.4 to 0.5% of the population [139]. However, the HBV prevalence of migrants to Ireland may be lower than the prevalence in the general population in their country of birth. The European Centre for Disease Prevention and Control (ECDC) reviewed studies which described in-country and migrant HBsAg prevalence estimates and found lower estimates for migrants in 34 of the studies, comparable estimates in 13 and higher estimates in 13 [135].

#### **Blood donors**

Of 365,133 first time blood donors tested by the IBTS between 1997 and 2020, 34 (0.009%) were found to be HBsAg positive (personal communication, IBTS, June 2021).

#### Pregnancy

Although there is currently no national collation and reporting of data on the prevalence of hepatitis B infection in pregnant women in Ireland, a report from the National Perinatal Hepatitis B Prevention Programme estimated that between 190 and 230 HBsAg positive women deliver infants in Ireland each year, giving an antenatal HBsAg prevalence of approximately 0.3%. This estimate was calculated using hepatitis B prevalence data from published studies in antenatal settings and maternity hospital annual reports, in combination with birth statistics from the Central Statistics Office and was mostly based on data from 2014 [140].

More recent antenatal testing data is available in annual reports from some maternity hospitals. The Coombe Women and Infant's University Hospital Annual Report for 2021 provides hepatitis B antenatal testing results from 2015 to 2021; the percentage of women testing positive for hepatitis B surface antigen ranged from 0.5% in 2015 to 0.2% in 2021 [141]. In 2021 0.4% of pregnant women tested positive for hepatitis B surface antigen in the Rotunda Hospital [142].

#### Groups at higher risk of HBV acquisition in Ireland

#### People who inject drugs and prisoners

The prevalence of HBsAg was found to be between 1% and 5% in studies of opioid users in Ireland carried out between 1992 and 2002 [143]. HBsAg prevalence was found to be lower than expected in a 2011 prison study in Ireland, with only 0.3% (n=2) of those screened testing positive [144]. In prison studies, in 1998, 1999 and 2017, the overall anti-HBC prevalence (current or past infection) was found to be 9%, 6% and 3%, respectively [145-147]. In the two studies carried out in the 1990s almost one fifth of prisoners with a history of injecting drugs tested positive for hepatitis B antibodies [144, 145]. Therefore, it is likely that a significant number of prisoners who had ever injected drugs were infected with hepatitis B in the past but did not develop chronic infection. Hepatitis B vaccine is also routinely offered to prisoners and drug users on opioid substitution treatment, so a large proportion are likely to have been vaccinated [147].

#### **Homeless people**

Five percent of homeless people reported that they had hepatitis B in studies carried out in Ireland in 2005 and 2013 [147]. However, this was self-reported and it is unclear whether it represents current or past infection.

#### **International Protection Applicants**

International protection applicants (IPA) and Beneficiaries of Temporary Protection (BoTP) are offered voluntary health screening in Ireland. Health screening is initially offered through a reception centre in Balseskin or a transit hub in Citywest. Over 2,600 IPAs were screened for chronic hepatitis B (HBsAg) in 2022 and 2.9% tested positive. This was similar to previously reported screening results from Balseskin; of almost 3,000 people tested between 2016 and 2018, 2.9% tested HBsAg positive (personal communication, HSE Social Inclusion).

#### Trends in hepatitis B infection in Ireland

Hepatitis B is a notifiable disease in Ireland. There was a significant increase in annual HBV notifications between 1997 (31 cases) and 2008 (896 cases), mostly attributable to large numbers of people immigrating to Ireland from HBV endemic countries. The annual number of notifications decreased by 42% between 2008 and 2011 (517 cases), but this decline has not continued and the notification rate has now stabilised, with an average of 480 cases notified annually between 2012 and 2022 [148]. In 2022, 517 cases of hepatitis B were reported, equating to an overall notification rate of 11/100,000 population. Where acute/chronic status was reported, 3% of cases were acute (recent) infections (0.3/100,000 population) and 97% were chronic (long-term) infections (8.5/100,000 population) [148].

Over two thirds of acute cases of hepatitis B notified between 2007 and 2022 (with information on risk factor) were sexually acquired (68%). Other reported risk factors for acute cases included being born in endemic country (no specific mode transmission reported) (8%), non-occupational needle/blood exposure (2%), tattooing/body piercing (2%), household contact with a case (1%), injecting drug use (1%) and dental work or surgical procedures (1%) [148]. Nosocomial exposures may have occurred in countries other than Ireland. Where information on country of birth was available, 70% of acute cases notified between 2007 and 2022 were born in Ireland, 10% were born in central or eastern Europe, 6% in Asia, 5% in western Europe (excluding Ireland), 5% in sub-Saharan Africa, 3% in Latin America and <1% in other regions.
Primary risk factor was not reported for most chronic cases of hepatitis B but country of birth or asylum seeker status was known for 58% of cases notified between 2007 and 2022. Of these, 79% were either born in an endemic country (HBsAg prevalence >2%) or were asylum seekers. Most are likely to have been infected at birth or during early childhood in their countries of origin. The most common regions of birth for chronic cases of hepatitis B were central or eastern Europe (36%), Asia (26%), sub-Saharan Africa (25%), Ireland (7%), north Africa and Middle East (3%), western Europe (2%) and Latin America (1%) [148].

Hepatitis B notifications are an underestimate of the true extent of hepatitis B in Ireland as chronic infections may remain undetected for decades and a large proportion of cases in Ireland are likely to remain undiagnosed. Between 2007 and 2022, where reason for testing was reported (69% of cases) most chronic cases of HBV in Ireland were diagnosed through screening of certain groups within the population such as; antenatal screening (26%), asylum seeker screening (17%) and STI screening (13%). Only 3% of cases were tested because they presented with symptoms [148].

Using Central Statistics Office census 2016 data on the population of Ireland by country of birth and published HBsAg prevalence data by country of birth [143], it was estimated that approximately 2.4% (n= 19,250) of people who had immigrated to Ireland were likely to have a chronic hepatitis B infection. However, this may be an overestimate as it is based on the assumption that the prevalence of HBsAg in migrants to Ireland is similar to that in the general population in their country of birth. A 2016 ECDC literature review of studies of hepatitis B in migrants found that the HBV prevalence in migrant populations was lower than that reported for their countries of birth in previously published prevalence studies [135].

## **Hepatitis C virus**

Hepatitis C infection is caused by an RNA virus that was first identified in 1989. Chronic hepatitis C (HCV) infection is a major cause of liver disease and liver disease-related death throughout the world. Globally, an estimated 58 million people are chronically infected with hepatitis C [149, 150].

In recent years, highly effective Direct-acting Antiviral Agents (DAAs) have become available, presenting major advancements in the treatment of Hepatitis C. DAAs demonstrate increased tolerability, safety and efficacy compared with interferon-based therapies, and if administered during the early stages of infection, DAAs can significantly reduce mortality associated with HCV disease. DAAs approved by the European Medicines Agency include sofosbuvir, belpatasvir, voxilaprevir, glecaprevir, pibrentasvir, grazoprevir and elbasvir, generally used in combination. Adding to their

desirability as a treatment option, many DAA combinations work in a pan-genotypic manner and therefore do not require genotype testing before administration [151].

Achieving a Sustained Virological Response (SVR) is the goal of HCV treatment. This is defined as undetectable HCV RNA (or undetectable HCV core antigen in patients with detectable HCV core antigen before treatment) at 12 or 24 weeks following treatment completion. DAAs achieve SVR in up to 95% of recipients, and eradicate the virus in 90% of patients [152]. An SVR corresponds with healing of liver injury and inflammation, normalisation of liver enzymes, and cessation or regression of fibrotic changes in liver morphology [151]. DAAs are typically contraindicated in patients with current or prior history of decompensated liver disease.

## Transmission

HCV is transmitted through blood and infection occurs primarily through shared equipment when injecting drugs. Less frequent modes of transmission include; sex with an infected partner, accidental exposure to contaminated blood in healthcare or other settings (needlestick injuries, re-use/inadequate sterilisation of medical or tattoo equipment) and mother to baby transmission [149, 150]. Transfusion-related HCV infection is rare in developed countries since the introduction of routine screening of donor blood for HCV antibodies in the early 1990s [153].

## **Clinical information**

In general, acute HCV infection is relatively mild and is frequently unrecognised. However between 60% and 85% of those infected develop chronic infection. Chronic HCV infection is marked by persistence of HCV RNA for at least 6 months after onset of infection. Spontaneous resolution after 6 to 12 months of infection is unusual [149]. Hepatitis C antibody (anti-HCV) is present in acute, chronic and resolved infection. Testing positive for HCV RNA or HCV antigen is an indication of HCV viraemia (current infection).

Those who become chronically infected are at risk of 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 between 5% and 40% of chronically infected individuals will develop cirrhosis of the liver after 20 to 40 years of infection. The annual risk of HCC in those with cirrhosis is estimated to be between 1.5% and 2.5% [154].

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 [149].

Highly effective treatments with direct-acting antiviral drugs (DAA) have been available in Ireland since late 2014. These treatments eradicate the virus in over 95% of cases [150].

### Prevalence of HCV infection in Ireland, Europe and the world

#### Hepatitis C infection worldwide

The estimated global prevalence of chronic HCV is 1%. 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 still likely to be the major modes of transmission. Countries with the highest reported anti-HCV prevalence rates are located in Africa, Asia, Eastern Europe and Central Europe. Intermediate prevalences are reported in southern European countries such as Greece, Spain and Portugal and lower prevalence countries include North America, northern and western European countries, and Australia [155]. The prevalence of viraemic infection is declining in many countries due to the roll out of DAA treatment.

#### **HCV in Europe**

According to data reported by the ECDC, there are 27,000 to 29,000 newly diagnosed cases in the EU/EEA each year [156]. In 2021, 14560 cases of hepatitis C were reported in 29 EU/EEA Member States. Of the cases reported, 7% were classified as acute, 35% as chronic, and 55% as 'unknown' [157]. Three percent could not be classified. In 2021 (as per ECDC data) the most commonly reported mode of transmission of HCV in Europe was injecting drug use, which accounted for 61% among acute cases and 70% among those classified as chronic with complete information on mode of transmission.

The ECDC reported in 2021 that overall notification rates were mostly higher in northern and western European countries than in southern European countries [157]. The rate of reported acute cases was 0.3 per 100 000 population, ranging from <0.1 per 100000 in Croatia, Cyprus, Denmark, Greece, Iceland, Malta, Poland, Romania, and Slovenia to 1.9 per 100000 in Sweden [157]. The notification rate of chronic cases was 1.9 per 100 000 population, ranging from <0.1 per 100000 in Latvia. The rate of cases classified as unknown ranged from 0.0 cases per 100000 population in Greece and Italy to 58.0 per 100000 in Luxembourg.

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. A 2016 systematic review reported that the reported number is possibly an underestimate of the real occurrence of HCV due to the asymptomatic nature of the infection [158].

## Ireland

The prevalence of HCV in the general population in Ireland is low. However, hepatitis C is more prevalent in certain sub-groups of the population, in particular people who inject drugs (PWID), migrants to Ireland from higher endemicity countries, recipients of blood or blood products in the past, gay, bisexual and other men who have sex with men and people who change sex partners frequently [159, 160].

## Groups at lower risk of HCV acquisition in Ireland

#### **Blood donors**

Blood donors would be expected to be an extremely low risk sub-group of the general population. Of 335,133 first time blood donors tested by the IBTS between 1997 and 2020, 50 (0.014%) were found to be HCV antibody positive. Antigen or RNA results were provided for 62,351 first time donors tested between 2016 and 2020 with one positive result (current HCV infection) (0.0016%) (personal communication, IBTS).

#### **General population**

A study based on laboratory diagnoses and statutory notifications of hepatitis C estimated the prevalence of chronic (viraemic/current infection) HCV infection in Ireland at the end of 2009 to be 0.5-1.2% [159]. This study took undiagnosed cases into account and It was subsequently felt that the estimates for undiagnosed cases of hepatitis C (50-80%) were too high.

This was supported by results from a pilot opt-out emergency department bloodborne virus screening programme in St James's Hospital (SJH), from March 2014 to January 2015. Patients who were undergoing blood sampling as part of their care were offered tests for hepatitis B and C and HIV. Of over 8,800 patients tested (50% uptake rate), 447 (5%) had a positive HCV antibody result. However only 13% (n=58) were previously undiagnosed cases [160]. SJH is located in inner-city Dublin and the catchment population would be expected to have higher HCV prevalence than the general population in Ireland.

Lower prevalence estimates were found in a study involving testing of residual sera specimens (from April 2014 to February 2016) from the National Virus Reference Laboratory. Based on this study the national prevalence of chronic HCV in adults in Ireland was estimated to be 0.57% (95% CI 0.4-0.8%) or just over 19,600 indivduals (95% CI 13,758-27,860) [161].

In late 2014, highly effective direct acting anti-viral drugs, with a greater than 95% cure rate, were approved for hepatitis C treatment in Ireland. Over 7,000 people in Ireland were treated with these drugs between late 2014 and early 2023. A 2022 modelling study has estimated the current prevalence of chronic HCV in the overall population in Ireland to be 0.21% (95% CI: 0.13-0.35) or 7,844 individuals (4,711-13,035) [162].

## Pregnancy

The decline in chronic HCV prevalence in Ireland is also evidenced in antenatal screening data. Antenatal screening for HCV in maternity hospitals was selective, based on identified risk factors, in Ireland until recently. However, universal voluntary screening was carried out in two large, Dublinbased maternity hospitals for one year periods as part of studies looking at hepatitis C prevalence in antenatal women and assessing whether universal screening should be implemented in Ireland. Uptake was very high in both studies and both involved testing approximately 9,000 women over a one year period. One of these studies was carried out in 2007 and found an anti-HCV prevalence of 0.7% and an RNA prevalence of 0.4% [163]. The second was carried out between June 2007 and June 2008 and found an anti-HCV prevalence of 0.9% and an RNA prevalence of 0.6% [164].

A more recent study tested specimens from 2018 from patients, in two large Dublin-based maternity hospitals, who had not been selected for HCV testing on the basis of a risk factor assessment. Of 4,655 specimens tested, 20 were antibody positive (0.43%) and 5 were antigen positive, reflecting viraemic infection (0.11%). The prevalence of viraemic HCV infection in 20,328 patients from 2016-2019 was 0.15%. This study found that there has been a 65% decline in the prevalence of Hepatitis C infection in pregnant women, in the maternity hospitals studied, in the past 15 years[165].

## Groups at higher risk of HCV acquisition in Ireland

#### People who inject drugs (PWID) and prisoners

Studies of opioid users in Ireland between 1995 and 2018 estimated the HCV antibody prevalence in this population to be between 52% and 84%. However, many of these studies were carried out several years ago and the cohorts studied mostly attended Dublin-based addiction treatment centres or GPs.

Available evidence suggests that the incidence of injecting and of HCV in drug users is declining in Ireland [143].

A national cross-sectional survey of Irish prisoners in 1998 found an anti-HCV prevalence of 37% in all prisoners, and of 81% in prisoners with a history of injecting drugs [145]. More recently, a 2011 prison study found that 13% of 777 prisoners tested for hepatitis C were anti-HCV positive. The hepatitis C antibody prevalence was much higher in those who injected drugs: 54% of prisoners with a history of injecting any drugs tested anti-HCV positive (80/149) and 41.5% of prisoners with a history of injecting any drugs tested anti-HCV positive (83/200) [144].

The prevalence of hepatitis C was found to be higher in a 2017 study of over 400 male prisoners in Mountjoy prison in Dublin. Just under one quarter (23%) of all prisoners tested positive for anti-HCV and he prevalence of viraemic infection was 13%. Seventy nine percent of those with a history of injecting drugs, tested anti-HCV positive [147].

## **Homeless people**

In studies carried out in 2005 and 2013, 36% [166] and 28.5% [167] of homeless adults self-reported that they had HCV, respectively. A further study was carried out in 2015 to determine the HCV prevalence in homeless people attending Safetynet primary healthcare services in Dublin. In this study, over 600 people were offered testing and 88% accepted. Of these, 40% tested positive for hepatitis C antibody. Over half were not aware of their positive status prior to testing [168].

## **International Protection Applicants**

International protection applicants (IPA) and Beneficiaries of Temporary Protection (BoTP) are offered voluntary health screening in Ireland. Health screening is initially offered through a reception centre in Balseskin or a transit hub in Citywest. Over 2,600 IPAs were screened for chronic HCV (antigen/RNA) in 2022 and 0.4% tested positive. This was lower than previously reported screening results from Balseskin; of almost 3,000 people tested between 2016 and 2018, 1% tested positive for chronic HCV (personal communication, HSE Social Inclusion).

## Trends in hepatitis C infection in Ireland

Hepatitis C became a notifiable disease in Ireland in 2004. Almost 17,000 cases (n=16,929) of hepatitis C were notified in Ireland between 2004 and 2022 [169]. The number of hepatitis C notifications peaked in 2007 (n=1536, 36 per 100,000 population) and decreased by almost 70% between 2007 and 2022 (n=483, 10 per 100,000 population). Information on risk factor or country of birth was available

for 59% of cases notified between 2007 and 2020, of whom 67% were PWID and 11% were born in endemic countries or were asylum seekers [160, 166]. Seventy percent of cases in 2022 cases were male and the median age at notification was 43 years. Trends in hepatitis C notifications are difficult to interpret as cases are frequently asymptomatic or mildly symptomatic for some time, and are more likely to be diagnosed as a result of screening in risk groups rather than presenting with symptoms. Therefore cases may be diagnosed years after infection and trends in notifications may not reflect trends in hepatitis C incidence well. However, there has been an overall decline in case numbers since 2007 and there have been changes in the age profile of cases, with a steady increase in median age over time (31 years in 2004, 43 years in 2022). This is likely to indicate a declining incidence of HCV in Ireland, with a significant proportion of more recently notified cases representing longer-term infections detected through screening rather than recent infections [150].

## **Human Immunodeficiency Virus**

The human immunodeficiency viruses were discovered in 1983 [170] and comprise two species of retroviruses from the genus Lentivirus, HIV type 1 and HIV type 2, collectively known as HIV (human immunodeficiency virus) [171]. HIV type 2 is most prevalent in Central and Western Africa and is typically uncommon outside these regions. 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 real-time quantitative reverse transcription polymerase chain reaction, or RT-PCR.

During this period of acute infection (also referred to as primary HIV infection, or the seroconversion illness), detectable HIV RNA levels peak, before declining over subsequent weeks [172]. The majority of HIV testing is now done using a combined Antigen/Antibody assay, 4<sup>th</sup> generation HIV test. This reduces the window period, the time period between becoming infected and developing a positive HIV test result. The current recommended window period is 45 days [173, 174].

The symptoms of acute HIV infection can last for between 7 and 10 days [180]. The patient may complain of symptoms resembling the "flu", or "glandular fever-type" infection [172]. Typical symptoms include fever, maculopapular rash, oral ulcers, lymphadenopathy, arthralgia, pharyngitis, malaise, weight loss and myalgia. Once these acute symptoms resolve, most patients enter an asymptomatic phase. This asymptomatic phase can last more than 10 years.

In untreated individuals following seroconversion, there is an asymptomatic phase of variable duration [172, 173]. Over the subsequent asymptomatic period, of variable duration, CD4+ T

lymphocyte levels gradually decrease. If levels of CD4+ T lymphocytes drop below 200-350 cells/ $\mu$ l, the patient is at increased risk of developing opportunistic infections.

In Ireland, antiretroviral therapy is recommended as soon as possible for all people following a HIV diagnosis, as effective antiretroviral therapy presents significant benefits to the individual, and in preventing onward transmission of HIV [175].

## Prevalence of HIV infection in Ireland, Europe and the world

## **Global HIV distribution**

At the end of 2021, an estimated 38.4 million people were living with HIV globally. The annual number of people newly infected with HIV has declined by 54% since its peak in 1996 although there is stark regional variation.

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%) [176].

Estimates of HIV prevalence globally among those with a history of PWID vary [177]. 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.

Information on the global distribution of HIV/AIDS can be found in the AIDSInfo collection on the UNAIDS website <u>here</u>. AIDSInfo, a collaboration of UNAIDS and UNICEF and the WHO, contains the world's most extensive and up-to-date information on HIV prevalence and epidemiology.

#### **HIV infection in Europe**

While epidemic patterns and trends vary widely across European countries, as in previous years, more men than women were diagnosed with HIV in 2021 (12,877 and 3,598, respectively), resulting in an overall male-to-female ratio of 3.6 : 1. The predominant mode of transmission in countries with the highest male-to-female ratios was sex between men accounting for 40% (6,648) of all new HIV diagnoses in 2021. Sex between men and women is the second most commonly reported mode of transmission in the EU/EEA, accounting for 29% (4,848) of all HIV diagnoses and three and a half per cent (586 cases) of all new HIV diagnoses and 5% of those with a known route of HIV transmission were attributed to injecting drug use [178].

#### Ireland

HIV became a notifiable disease in Ireland in September 2011 and since January 2012 HIV data are reported through the Computerised Infectious Disease Reporting (CIDR) system. Case based reporting of HIV cases has been in place since 2001 [179].

In 2019, a total of 532 newly diagnosed cases were reported in Ireland, a rate of 11.2 per 100,000 population. This decreased by 17% in 2020 with 444 notifications at a rate of 9.3 per 100,000 population. In 2020, where the route of transmission was known, gay and bisexual men who have sex with men (gbMSM) represented the highest proportion of newly identified HIV cases at 27.5% of overall notifications (n=122). This was followed by heterosexual transmission at 14% (n=64) and PWID at 2% (n=9). The route of transmission was unknown in the remaining 249 cases, although it is noted that data reporting may have been impacted by the COVID-19 pandemic. The majority (79%) of new cases in 2020 were identified in males and people who identify as male (n=352).

Annual numbers of new diagnoses of HIV in Ireland have fluctuated between 300 and 400 over the past decade. A change in the case definition for surveillance, which was introduced in 2015 in HSE East (Dublin, Kildare and Wicklow) and to all other areas in 2016, improved both the timeliness of notifications and resulted in an increase in the number of notifications in recent years [180]. 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 gbMSM continues to rise year on year since 2005 [179].

#### HIV acquisition in particular groups in Ireland

#### **Blood donors**

Of 313,019 first time blood donors tested by the IBTS between 1997 and 2015, 14 (0.0045%) were found to be living with HIV. (Personal communication, Dr Joan O'Riordan, IBTS, July 2016). The risk of HIV-1 infection through blood transfusion has been calculated by the IBTS at about 1 in 15 million donations transfused. The detection of HIV-2 is an extremely rare event with no reported cases in the IBTS to date [181].

## Pregnancy

HIV screening is offered routinely to all pregnant people in Ireland under a voluntary antenatal HIV testing programme that was introduced in 1999. In 2019, the national reported uptake of HIV antenatal screening (from 19 hospitals) was almost 100%. The HIV prevalence rate among pregnant

people in Ireland was 0.14% in 2019, which was slightly lower than the rate in 2018 (0.17%). The prevalence of HIV infection among pregnant people varied by maternity hospital/unit, ranging from 0% to 0.39% [62]. A 2024 epidemiological study (currently unpublished) suggests that the prevalence in the birth cohort 1965-1985 in GP bloods is approximately 0.01%. [182]

#### People who inject drugs (PWID)

Between 1985 and 2017, 1,645 diagnoses of HIV among PWID have been reported which account for 18.6% of total HIV notifications. Between 2004 and 2011, the number of diagnoses of HIV among PWID steadily decreased (from 74 to 17) until 2015 where an outbreak of HIV occurred among PWID in Dublin [143]. According to a 2018 report on bloodborne viruses in intravenous drug users published by the HPSC, PWID are more likely to be diagnosed at a late stage of infection compared to other risk groups, and 8% of newly diagnosed PWID between 2012-2017 presented with an AIDS-defining illness.

In 2015 in the HSE East region there was an outbreak of new HIV diagnoses in PWID related to injection with a psychoactive substance called 'snow-blow.' From January 2014 to December 2015, 39 cases of recently acquired HIV among PWID were identified. Fifty nine percent were male and the median age was 35 years (range: 20-51 years). The majority (74%) of cases were registered as homeless (94% of females and 61% of males). Seventy four percent had hepatitis C co-infection [143].

In 1997, 17% of a group of PWID in the HSE eastern region, who were attending methadone clinics, tested positive for HIV infection [183]. 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% [184].

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 [185]. A study carried out among socially excluded drug users in 10 European cities in 1998-2000 found a self-reported HIV prevalence of 24.6% in Dublin, the second highest of the cities [186].

#### Sexualised drug use

Sexualised drug use is the use of drugs within a sexual context and has attracted interest due to the role it could play in increasing exposure to the transmission of HIV. Sexualised drug use encompasses 'chemsex' which describes the use of specific drugs before or during planned sex to facilitate, initiate, sustain, prolong and intensify the encounter [187]. Drugs associated with chemsex include ecstasy/MDMA, cocaine, ketamine, amphetamine, crystal meth and ephedronema [188]. In the 2017

European Men Who Have Sex with Men Internet Survey (EMIS) Ireland Project [189], 20% of the total respondents reported to have ever used stimulant drugs to make sex more intense or last longer, while 14% had used stimulant drugs within the previous 12 months. It should be noted that chemsex was not specifically asked about throughout this survey, however, the use of stimulant drug use during sex was used as a proxy for chemsex. In a 2018 UK survey of 836 gbMSM attending sexual health clinics, 17% reported sexualised drug use in the last 6 months and 10% reported injecting ("slamming") chemsex drugs in the last 6 months [63]. Qualitative and observational evidence suggests sex parties involving group sex and use of club drugs has contributed to the high rate of new HIV and hepatitis C infections, including in a subset of chemsex users, transmissions through intravenous use of crystal methamphetamine or mephedrone ('slamming') by inexperienced users or through deliberate sharing of blood injecting equipment [64]. This can lead to the potential exposure of HIV and other BBVs, therefore individuals who report drug use in a sexual context should be asked about injecting and sharing equipment [65].

#### Prisoners

HIV is more prevalent in the prison population compared with the general population. Between 1987 and 1991, 168 people living with HIV were incarcerated in Mountjoy Prison in Dublin, comprising 16.6% of the known population of people with HIV at the time [190]. 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 [145].

Since 2007 a HIV and sexually transmitted infection (STI) consultant-delivered in-reach service has been provided by the Department of Genito Urinary Medicine and Infectious Diseases (GUIDE) at St James's Hospital, Dublin. This service serves various correctional facilities across Ireland including Cloverhill, Wheatfield, and Mountjoy Prisons {Point-of-care testing for HIV in an Irish prison setting: results from three major Irish prisons}

## **Asylum seekers**

Screening of asylum seekers in the HSE eastern region 2000-2003 found a prevalence of anti-HIV of 2.2% [191].

Please see <u>Table 3 *HIV transmission risk by exposure type*</u> for more information.

## Appendix 2 Saliva and bloodborne viruses

## Pathophysiology

In a closed-fist exposure ("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 exposure, tendons and their overlying sheaths are in close proximity to the skin. The wound may appear to be a minor abrasion-type exposure, but careful inspection is required to rule out deep exposure.

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.

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 exposure ("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.

#### Infection

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, Staphylococcus aureus* and *Eikenella corrodens*) and anaerobic bacteria (such as *Fusobacterium, Peptostreptococcus, Prevotella*, and *Porphyomonas* spp.) [192].

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 an individual from a group with higher HIV prevalence than the general population, 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.

## 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 a 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 [193]

## History

- Circumstances of the exposure
- Time of exposure (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 exposure
- 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 [194]. 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 [195]. Prophylactic antibiotics should be given for human bites if any of the following are present:

- All human bites less than 3 days old, puncture or crush wounds; wounds that require surgical debridement or involving joints, tendons, ligaments or fractures.
- Wounds that have undergone primary closure.
- People at risk of serious wound infection (e.g. those who are immunocompromised, diabetic, asplenic, cirrhotic).
- People with a prosthetic valve or prosthetic joint.

Please see the **Bite (Human/Cat/Dog) Antibiotic Treatment** table on the HSE antibiotic prescribing website <u>here</u>.

Tetanus prophylaxis may be indicated.

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

## Appendix 3 Prescribing information for emergency contraception

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?

- 1. in females presenting for post-exposure prophylaxis (or consideration of same) following potential sexual exposure to BBVs
- in females presenting for assessment following sexual assault (Please see <u>here</u> for other considerations in 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 hours of condomless, PrEP-less sexual intercourse.

#### **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 [196]. If administered immediately before ovulation UPA has been shown to suppress growth of lead follicles [13, 79]. There is evidence [13] to suggest that UPA can prevent ovulation after the IH surge has started, delaying follicular rupture until up to 5 days later. Administration of UPA at the time of the IH peak or after has been shown to be ineffective in delaying follicular rupture [13]. Although there have been studies that have shown an endometrial effect [197, 198], 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 reported to date [196].

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 condomless, PrEP-less sexual intercourse. The efficacy of UPA has been demonstrated up to 120 hours after condomless, PrEP-less sexual intercourse [196, 199, 200], and there is no apparent decline in efficacy within that time period [199]. No data are available on the efficacy of ellaone when taken more than 120 hours (5 days) after condomless, PrEP-less intercourse.

#### What is the dose?

A single dose of UPA 30mg tablet is given orally [196].

If vomiting occurs within 3 hours of ellaone intake, another tablet should be taken [196].

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) [196].

The FSRH Guidelines (2011) do not currently support doubling the dose of UPA when using drugs that may reduce UPA's efficacy [201].

## 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 [196].

- 1. The SPC states that contraindications to use include a hypersensitivity to UPA or any of the other components, and also pregnancy [196].
- 2. Use is not recommended in women with severe asthma insufficiently controlled by oral glucocorticoids.
- 3. The SPC advises caution in women with hepatic dysfunction, hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose-galactose malabsorption [196].
- The SPC states that after intake of UPA, breastfeeding is not recommended for up to 36 hours [196].

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

Please refer to the <u>Faculty of Sexual and Reproductive Healthcare website</u> or the <u>Summary of Product</u> <u>Characteristics</u> for further information.

### Emergency Contraceptive Pill (ECP): Levonorgestrel (NorLevo® or Prevenelle®)

#### How does levonorgestrel prevent pregnancy?

The exact mode of action of levonorgestrel in preventing pregnancy following condomless, PrEP-less sexual intercourse 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 [202] showed that a 1500 microgram single dose of levonorgestrel (taken within 72 hours of condomless, PrEP-less sexual intercourse) prevented 82% of expected pregnancies.

#### When can levonorgestrel be given?

Levonorgestrel should be given as soon as possible after condomless, PrEP-less sexual intercourse. It is most effective when given within 72 hours of condomless, PrEP-less sexual intercourse. Efficacy is reduced after this time [203, 204].

Use of levonorgestrel between 73 and 120 hours post condomless, PrEP-less sexual intercourse 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 circumstances 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 condomless PrEP-less sexual intercourse [203, 204]. 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 [203, 204].

Medicines containing levonorgestrel may increase the risk of cyclosporin toxicity due to possible inhibition of cyclosporin metabolism [203]. For 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 [205]. 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

- 1. 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.
- 2. The WHO Medical eligibility Criteria for Contraceptive use advises that there are no medical contraindications to levonorgestrel [206].
- 3. The SPC (summary of product characteristics) for Prevenelle and Norlevo state that levonorgestrel is not recommended in patients with severe hepatic dysfunction [203, 204].
- 4. 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 [203, 204].
- 5. Women with severe malabsorption syndromes (such as Crohn's disease) may experience a reduction in efficacy of oral emergency contraception [203].
- 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. [207].

## **Additional resources**

For time frames for prescribing emergency contraception, please see the <u>National Guidelines on</u> <u>Referral and Forensic Clinical Examination Following Rape and Sexual Assault (Ireland)</u>, Table 10, Page 102.

For patient information leaflet on emergency contraception, see here.

## Appendix 4 Useful contact information

Please find contact details for Public Health Areas on the HSE website here.

For Sexual Assault Treatment Unit (SATU) contact details please see here.

For a list of HSE STI/GUM clinics in Ireland please see here.

## Hospitals with Infectious Diseases/Genitourinary Medicine Departments

Name	Phone	Website
University Hospital Limerick	(061) 301 111	Link
University Hospital Galway	(091) 524 222	Link
Cork University Hospital	(021) 492 2000	Link
St James's Hospital (the GUIDE clinic)	(01) 416 2315	Link
Mater Misericordiae University Hospital	(01) 803 2063	Link
Beaumont Hospital	(01) 809 3006	Link
	(01) 809 2211	
St. Vincent's University Hospital	(01) 221 3363	Link

## **Children's hospitals with Infectious Disease departments**

Name	Phone	Website
Children's Health Ireland (CHI) Crumlin	(01) 409 6100	<u>Link</u>
Children's Health Ireland (CHI) Temple Street	(01) 878 4200	<u>Link</u>

## Other useful contacts

Name	Phone	Website
Health & Safety Authority	0818 289 389	Link
National Virus Reference Lab (NVRL)	(01) 716 4401	Link

## Appendix 5 Conflict of interest and funding

## **Conflict of interest statement**

The process for updating the recommendations in this guideline followed the Health Service Executive (HSE) conflict of interest policy. All members of the GDG completed a HSE declaration of interest form. Confidentiality and declarations of interest were collected and reviewed. No conflicts of interests were identified.

## Funding

The RGDU was commissioned by the Health Protection Surveillance Centre to undertake the work on this guideline. No funding was received for the development of this guideline.

## **Appendix 6 Consultation process**

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

Academy of Medical Laboratory Science The Nursing and Midwifery Board of Ireland (Formerly 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 Royal College of Physicians of Ireland Royal College of Surgeons in Ireland

Sexual Assault Treatment Units Specialists in Public Health Medicine

## 2024 Update

A public consultation on the recommendations for HIV PEP was carried out between the 8<sup>th</sup> and 22<sup>nd</sup> of February 2023. A summary of the updated HIV PEP recommendations was available on HPSC website for comment and feedback during this time. Notice of the launch of the consultation was communicated to a distribution list and posted on social media.

## Appendix 7 Glossary of abbreviations and terms

## Abbreviations

Ab Antibody Ag Antigen AGREE II Appraisal of Guidelines for Research and Evaluation Instrument **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) SW 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 gbMSM Gay and bisexual men who have sex with men **GDG** Guideline Development Group **GP** General practitioner **GUM** Genitourinary medicine **GRADE** Grading of Recommendations Assessment, Development and Evaluation **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 Health and care 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 n/a not available; not applicable 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 PRISMA Preferred Reporting Items for Systematic Review and Meta-analysis PCR Polymerase chain reaction **PEP** Post-exposure prophylaxis PEPSE Post-exposure prophylaxis for sexual exposure **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 **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 exposure. 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.

## **Appendix 8 Acknowledgements**

## 2022-2024

The guideline development group is very grateful to the individuals and organisations who assisted in the updating of these guideline recommendations. The group is also appreciative of those who provided feedback on the consultation document.

## 2018

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

## Appendix 9 Guideline development group members

Members of the guideline development group (and where applicable, the organisations they represented)

#### Guideline development group members (2022-2024 update)

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