CUH
Ospidéal Ollscoil Chorcaí
Cork University Hospital
Departments of Infectious Diseases &
Emergency Medicine

POST EXPOSURE PROPHYLAXIS

GUIDELINES
Update, Oct 2013

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Adapted from Irish National PEP Guidelines, St James's Hospital Guidelines, and Guidelines for the Emergency Management of Injuries (HPSC, Sept 2012).

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INTRODUCTION

These guidelines aim to standardise the approach, assessment and treatment of patients presenting for the first time post:

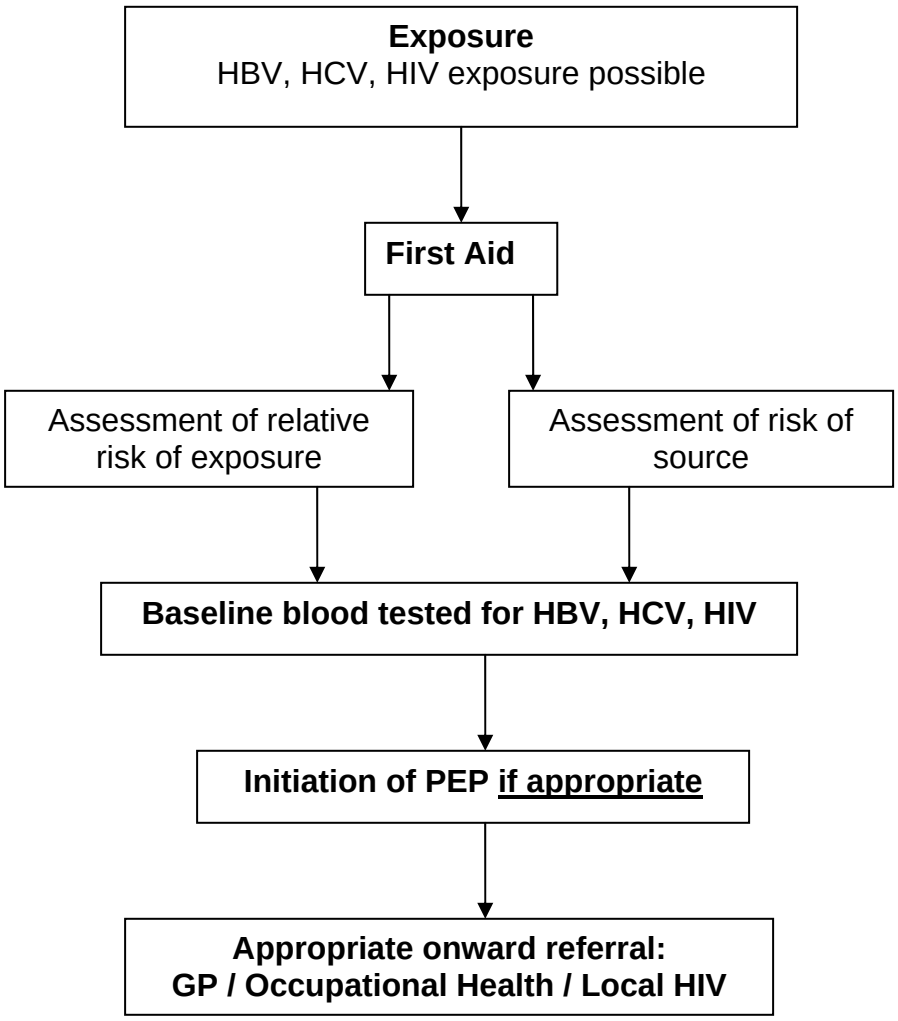
- Needle Stick Injury (NSI)
- Non Occupational Exposure
- Sexual Exposure

to a source who may be infected with a "blood borne virus" such as Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).
The aim is to ensure that appropriate assessment has been made and timely treatment initiated where appropriate. The patient should then be referred on for appropriate follow up.

Additional consideration for e.g. Tetanus immunisation may be relevant.
This is not covered in this document.

Attention should also be brought to the national publication from September 2012, The Emergency Management of Injuries, which is available at http://www.hpsc.ie/hpsc/A-Z/EMIToolkit/EMIToolkit.pdf This gives a very comprehensive overview of post-exposure prophylaxis. A major difference between these guidelines and the Emergency Management of Injuries Guidelines relates to the first choice of medication to be used for HIV PEP.

OVERVIEW



INITIAL MANAGEMENT OF PATIENT PRESENTING TO CUH ED FOR PEP or PEPSE

If a patient presents to ED Triage for PEP Mon-Fri 9am-4.30pm, the triage nurse should contact ID CNS (087 6996272) or ID SpR (bleep 203).

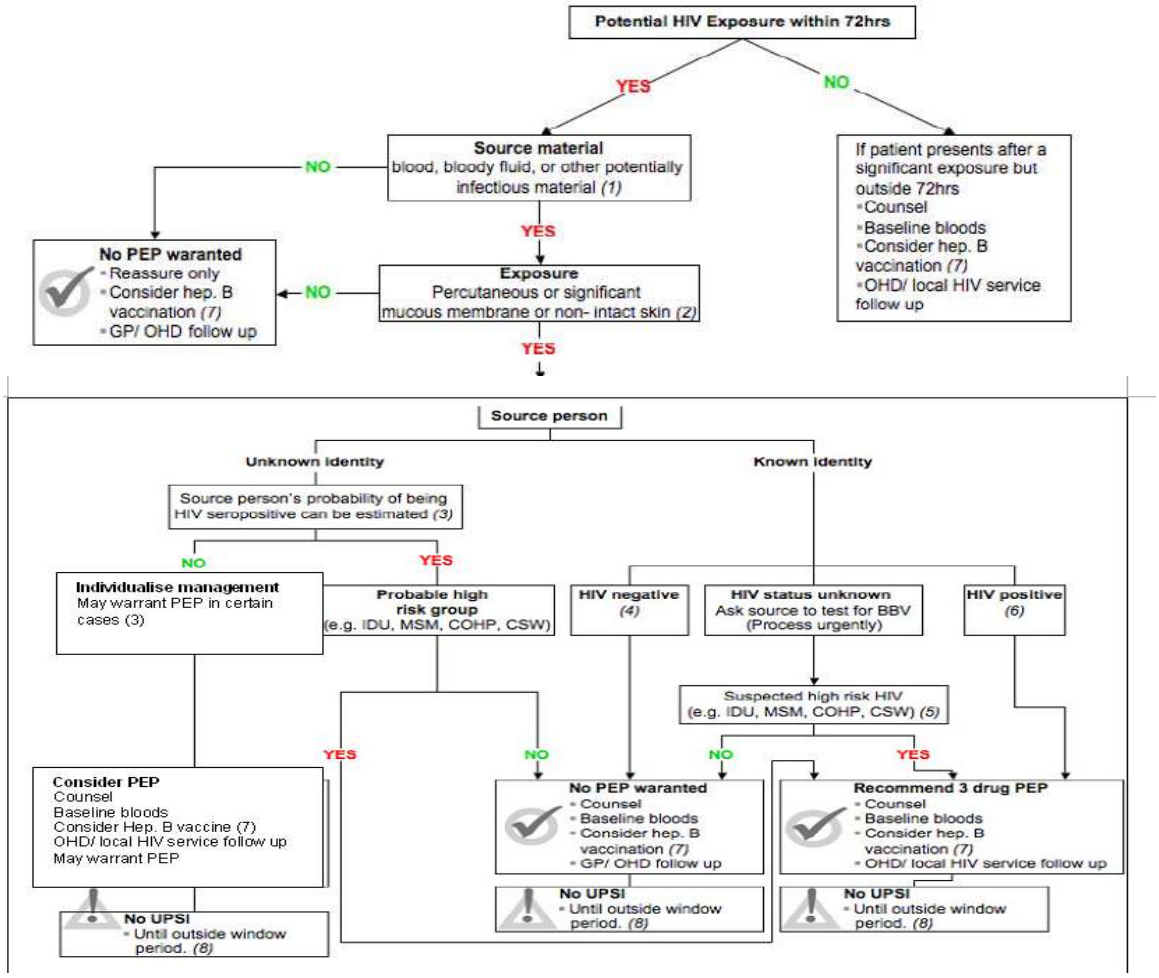
Outside of these hours this protocol should be used to assess the need for a HIV-PEP starter pack which should be dispensed and administered to patient if warranted. Follow-up with Infectious Diseases is extremely important and should be arranged as detailed below prior to the patient leaving the Department. Patients will be seen in the

next ID clinic. For staff members following occupational injury, follow-up should be organised with Occupational Health.

To arrange follow-up with ID prior to patient's discharge from ED:

- Call the phone of the ID CNS (087 6996272) and leave voice-mail with patient's name, MRN, and brief case details, stating that patient should be booked into next clinic.
- Send overview referral letter to ID secretary via FAX (021-4921343) or delivering the letter in person to the ID office (**not to rely on internal post**)
- Patients should be given the contact details of the ID CNS (087 6996272) as a direct contact person in the ID department and should be advised to call them during working hours for counselling issues or questions due to medications/side effects.
- Print Patient Information Leaflet (Appendix 2) and provide to patient.

PEP ASSESSMENT FOR HIV PEP (see also Tables 1, 2, 3)
See accompanying footnotes on following page



Abbreviations
BBV: Blood borne virus
COHP: Country of high prevalence (of infection being discussed)
CSW: Commercial sex worker
GP: General practitioner/ primary care physician
IVDU: Intravenous drug user
OHD: Occupational Health Department
MSM: Man who has sex with men
PEP: Post Exposure Prophylaxis
UPSI: Unprotected sexual intercourse

FOOTNOTES FOR HIV RISK ASSESSMENT

1) **Potentially infectious material:** semen or vaginal secretions, blood, CSF, synovial, pleural, peritoneal, pericardial or amniotic fluids or tissue.
NOT saliva, urine or faeces, unless mixed with blood.

2) **Exposure type:**

i) ***Percutaneous***

A more severe percutaneous exposure is associated with large bore, hollow needle, deep puncture, visible blood on device, or needle used in source patient's artery/vein.

Less severe percutaneous exposure. E.g. solid needle or superficial scratch.

Of note, outside the body HIV and Hep. C virus dry, die and become noninfectious within a few hours. Hep. B virus however can remain infectious for several days.

ii) ***Significant mucous membrane or non intact skin exposure***

Minor exposure: e.g. few drops for a duration of less than 1 minute.

Major exposure: more than few drops/ major splash and /or duration of several minutes or more.

Cutaneous exposure: is significant only if skin is compromised i.e. chapped, abrasion, open wound or dermatitis. Assess skin integrity.

iii) ***Human bites***

The risk of HIV or HCV transmission associated with saliva is exceptionally low and HIV PEP is only extremely rarely warranted, even if the source is known to be HIV positive. If there is known or suspected to be blood in the mouth of the biter at the time of the bite, then HIV PEP may be considered, if the biter has significant risks for HIV.

iv) ***Sexual exposure***

Whilst unprotected receptive vaginal sex is less risky than unprotected receptive anal sex, inherently it carries a risk and PEP should be considered just as seriously as a needle stick injury. There are however some differences.

v) ***Sexual assault***

PEP should be strongly considered if there has been a significant exposure (within past 72 hours) to a potentially infectious material, i.e. the source should be considered high risk for blood borne virus. Patient should be encouraged to attend the Sexual Assault Treatment Unit in SIVUH [Monday – Friday, 0830-1630 hrs. contact Finola Tobin 4926297 or Bleep 789. Out of hours or week-ends contact Nursing Admin. 4926100].

3) **Source unknown HIV status**

In exposures involving a source person with either unknown HIV status or unknown identity, it is not possible to give reassurance that the risk of HIV seroconversion is zero. However it may be possible to estimate risk e.g. is the source from high risk group e.g. IVDU, MSM, CSW, COHP of HIV?

Or

Is the source from a high risk environment?

A needle stick injury involving a sharps bin on a geriatric ward not known to have any HIV patients is very unlikely to be a major HIV risk group, unless information to the contrary is available. Discussion of pros/ cons of PEP is important to explore. There are potentially serious life threatening drug related adverse reactions to PEP which may exceed the HIV seroconversion risk. Treatment should be tailored to patient.

4) **Source is considered HIV negative**

if there is a HIV negative result within the past 3 months PLUS no clinical indication of a seroconversion like illness PLUS no recent high risk behaviour.

5) **The exposure**

should be outlined to the source (where known) and consent requested for blood to test for HIV, HBV and HCV.

6) **Source is considered HIV positive**

if they have a positive HIV result, or a physician has diagnosed HIV or the source self reports a diagnosis of HIV. A low or undetectable HIV viral load greatly diminishes the risk of transmission, but does not completely eliminate the risk.

7) **Hepatitis B and C**

is much more infectious than HIV and there is a vaccine available. All attendees should be offered Hep B vaccination unless they have known immunity. Hep B IV IgG should ONLY be administered when the source is KNOWN to be Hepatitis B surface antigen positive. Administration can be delayed up to 7 days. See hepatitis B algorithm. There is no prophylaxis for Hepatitis C; follow up bloods should be performed by follow-up physician.

8) **Window period: (advise patient to use condoms until outside the "window period")**

- ***If NO PEP taken (e.g. arriving too late for PEP, or refusing PEP):*** A negative HIV result at 6 weeks is very reassuring, but a HIV test should be performed 12 weeks after the incident, the result of which can be considered conclusive. The accepted window period for Hepatitis B, syphilis and Hepatitis C is also 12 weeks.
- ***If PEP taken:*** The window period is extended if the patient takes PEP. A HIV test should be performed 12 weeks ***after the end of PEP*** and the results of this should be considered as conculsive. In these circumstances onward referral to a specialist is expected to have occurred.

TABLE 1: ESTIMATED RISK OF HIV TRANSMISSION PER EXPOSURE: *FROM SOURCE KNOWN TO BE HIV POSITIVE*

(from EMI Guidelines, Sept 2012)

Table 1 Risk of HIV transmission following an exposure from a known HIV-positive individual

(Adapted from BASHH UK Guideline for use of HIV PEPSE 2011[4] – source references omitted from table)

Type of exposure	Estimated median (range) risk of HIV transmission per exposure (%)
Receptive anal intercourse	1.11 (0.042-3.0%)
Insertive anal intercourse	0.06 (0.06-0.065%)
Receptive vaginal intercourse	0.1 (0.004-0.32%)
Insertive vaginal intercourse	0.082 (0.011-0.38%)
Receptive oral sex (giving fellatio)	0.02 (0-0.04%)
Insertive oral sex (receiving fellatio)	0
Blood transfusion (one unit)	(90-100%)
Needlestick injury	0.3 (95% CI 0.2-0.5%)
Sharing injecting equipment	0.67
Mucous membrane exposure	0.63 (95% CI 0.018-3.47%)*
Human bite†	Very low risk. Case reports only

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

*The (BASHH) writing committee has concern regarding the risk estimate following mucous membrane exposures, which is derived from a single study including only small numbers of health-care workers exposed to HIV following mucous membrane exposures. This is likely to significantly overestimate the risk

†Not contained in BASHH Guidelines table

TABLE 2: ESTIMATED RISK OF HIV TRANSMISSION PER EXPOSURE: *FROM SOURCE OF UNKNOWN HIV STATUS*

(from EMI Guidelines, Sept 2012)

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

Type of exposure	Population group (% HIV prevalence)	Risk of HIV transmission - source HIV status unknown	Rounded off estimated risk per exposure (compared with risk if source known HIV+)
Receptive anal sex MSM*	MSM in Ireland (10%)[6]	0.1x1.11%=0.111%	1/900 (1/90)
Insertive anal sex MSM*	MSM in Ireland (10%)[6]	0.1x0.06%=0.006%	1/16,666 (1/1667)
Receptive oral sex MSM*	MSM in Ireland (10%)[6]	0.1x0.02%=0.002%	1/50,000 (1/5000)
Receptive vaginal sex	Heterosexuals in Ireland (0.2%)[7]	0.002x0.1%=0.0002%	1/500,000 (1/1000)
NSI‡ from unknown non high risk hospital pt	Heterosexuals in Ireland (0.2%)[7]	0.002x0.3%=0.0006%	1/166,667 (1/333)
NSI‡ from community source	IDU§ in Ireland (5 to10%)[8,9,§]	0.05x0.3%=0.015 to 0.1x0.3%=0.03%	1/6,667 to 1/3,333 (1/333)

*MSM=men who have sex with men

‡NSI=needlestick injury

§IDU=injecting drug user

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

It is generally recommended that HIV PEP is only offered when the estimated transmission risk is 1 in 1000 or greater, but all cases are considered on a case-by-case basis.[4] PEP can be considered in those with a risk of between 1 in 1,000 and 1 in 10,000 only in very exceptional circumstances.

There are a number of factors which may further reduce the risk of transmission e.g. HIV viral load <50, old dry blood. Other factors which increase risk of transmission e.g. high HIV viral load, intercurrent STI. In the UK, there has been no documented HIV seroconversions in health care workers following occupational exposure since 1999.

Table 3: PEP and PEPSE Recommendations by scenario

(from EMI Guidelines, Sept 2012)

	Source HIV status			
	HIV-positive		Unknown, from high prevalence group/ area*	Unknown, from low prevalence group/area
	Viral load detectable	Viral load undetectable		
Receptive anal sex	Recommend	Recommend	Recommend	Not recommended
Insertive anal sex	Recommend	Not recommended	Consider†	Not recommended
Receptive vaginal sex	Recommend	Not recommended	Consider†	Not recommended
Insertive vaginal sex	Recommend	Not recommended	Consider†	Not recommended
Fellatio with ejaculation ‡	Consider	Not recommended	Not recommended	Not recommended
Fellatio without ejaculation‡	Not recommended	Not recommended	Not recommended	Not recommended
Splash of semen into eye	Consider	Not recommended	Not recommended	Not recommended
Cunnilingus	Not recommended	Not recommended	Not recommended	Not recommended
Sharing of injecting equipment	Recommend	Not recommended	Consider	Not recommended
Human bite§	Consider** in very limited circumstances (see Bite algorithm, appendix 6)	Not recommended	Not recommended	Not recommended
Needlestick from a discarded needle in the community			Consider in very limited circumstances** (see Needlestick/Sharps algorithm, appendix 3)	Not recommended
Needlestick direct from source**	Recommend	Not recommended	Consider	Not recommended
Blood splash to non-intact skin, eye or mouth**	Consider	Not recommended	Not recommended	Not recommended

GUIDELINES FOR PRETEST COUNSELING

- Testing for HIV, HBV and HCV is a routine part of management following potential exposure. Baseline bloods reflect the patient's pre-existing status. This is not a test for seroconversion related to this exposure.
- The attached proformas identify risk factors for blood borne virus acquisition.
- Follow up bloods & care will be performed either with GP, OHD or local HIV clinic.
- Advise patients they should contact their GP/OHD/ HIV clinic if they develop any symptoms of acute viral illness.
- All patients should be advised to use barrier contraception (male condoms) until all follow up blood results are available.

HIV PEP PRESCRIBING DETAILS

- Only start PEP for HIV prevention if the patient presents within **72hrs of the exposure.**
- Once prescribed the 1st dose should be taken as quickly as possible, **i.e. take immediately in ED.**
- These drugs are not available in community pharmacies and can only be dispensed by hospitals, so you must give the patient the medication (not a prescription).
- The treatment duration is 28 days, however a 7-day starter pack is provided until the patient is seen by Occupational Health or their local HIV clinic.
- GI side effects are uncommon; nausea may occur with *Truvada*. Severe side effects are uncommon, but include renal impairment, neutropenia and hepatotoxicity.
- Treatment in pregnancy is recommended as Truvada 1 tablet od and Kaletra 2 tablets bd (as there is little data on raltegravir in pregnancy).
- Discuss with Emergency Medicine/Infectious Diseases Senior doctor if in doubt as to appropriate management.

PEP (Non-pregnant patient): Total 3 tablets per day

Truvada [Tenofovir + emtricitabine (FTC)] one blue tablet once daily +
Raltegravir one light pink tablet twice daily

PEP (Pregnant patient): Total 5 tablets per day

Truvada [Tenofovir + emtricitabine (FTC)] one blue tablet once daily +
Kaletra two yellow tablets twice daily

The starter pack contains enough meds for 7 days.
The course of treatment is 28 days so the patient ***must*** *attend Occupational Health or local HIV service for follow up and must not miss any medications.*

Kaletra may cause abdominal bloating, nausea. This may be overcome with Motilium [domperidone] 10mg 30 minutes pre- Kaletra.
Diarrhoea is also common initially and prescribing Immodium [loperamide] may improve symptoms. Ideally take with food.

For patients with a known HIV positive contact, their PEP prescription will be individually tailored *based on the source patient's treatment and resistance profile.* ***This must be discussed with a HIV specialist***

HIV PEP FOLLOW- UP

Hospital Occupational Exposure:

- follow up via local Occupational Health Department. Patient should not run out of medication.

Occupational Exposure but with no Occupational Health Department & PEP prescribed:

- follow up via local HIV clinic. Patient should not run out of medication.

Non occupational exposure & PEP prescribed:

- follow up via local HIV clinic. Patient should not run out of medication.

Patients with a moderate/ high risk exposure/source REGARDLESS whether PEP prescribed:

- follow up in local HIV clinic.

Patients who are low risk/unsuitable for PEP:

- follow up GP.

To arrange follow-up with ID prior to patient's discharge from ED:

- Call the phone of the ID CNS (087 6996272) and leave voice-mail with patient's name, MRN, and brief case details, stating that patient should be booked into next clinic.
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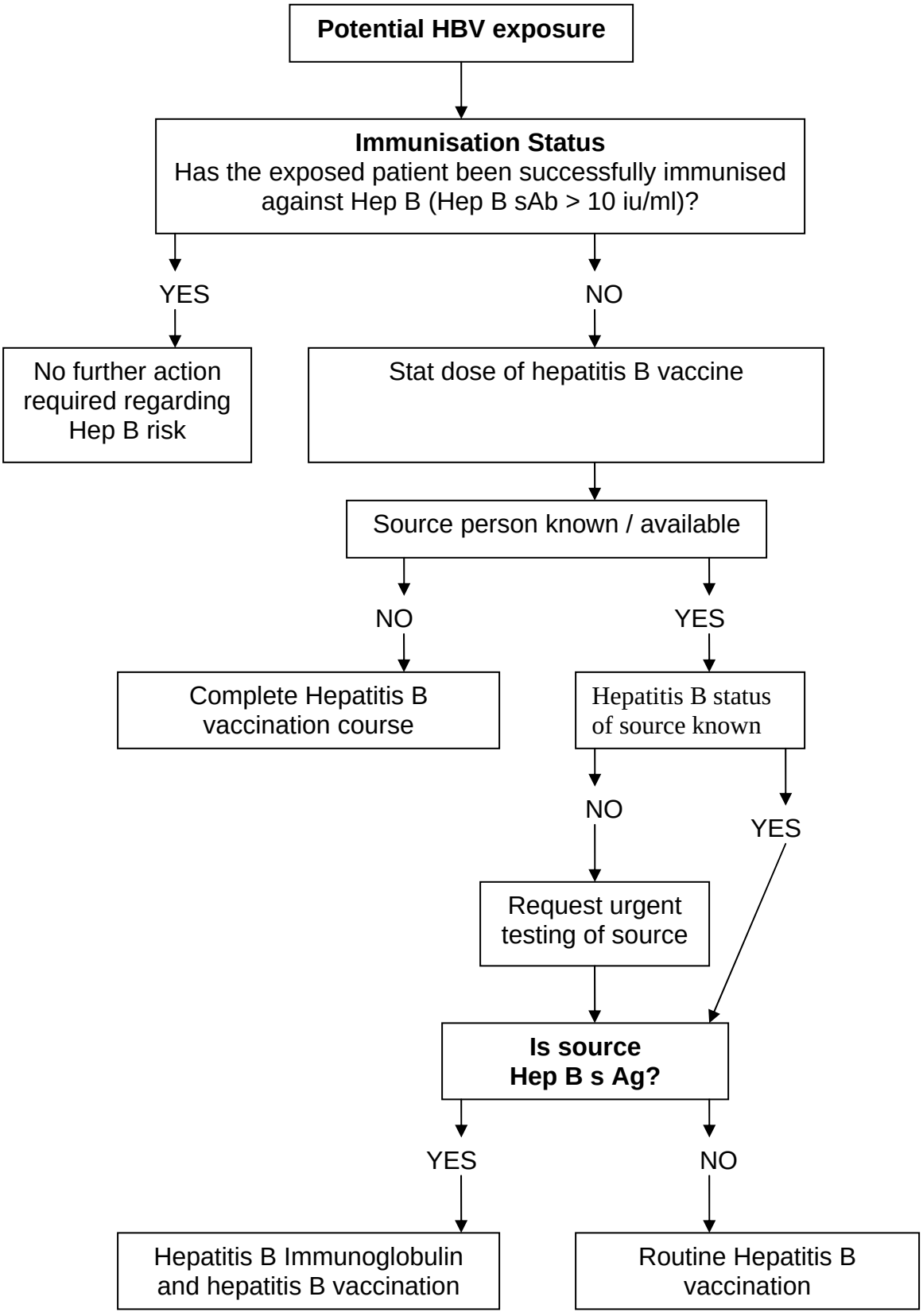
PEP for HEPATITIS B VIRUS



PEP for HEPATITIS B VIRUS

- **The vaccine is relatively safe, including in pregnancy**– it is unnecessary if the patient has been adequately vaccinated.
- Hepatitis B Immunoglobulin (Hepatect) is produced from blood donors, and treated to inactivate virus present. There is a risk of contamination e.g. other unknown viruses, CJD etc.
- **Hepatitis B IgG should only be prescribed when the source is known to be HepB sAg positive.**
    - The prevalence of Hepatitis B in Ireland is too low to warrant giving Hepatitis B IgG to patients where the source is unknown. The prevalence of Hepatitis B core Ab positivity in blood donors in Ireland is 0.51%, increasing to 6% in prisoner/ IVDU populations. However the prevalence of chronic active infection with Hepatitis BsAg positivity is substantially less.

HEPATITIS B VIRUS PRESCRIBING DETAILS

Hepatitis Vaccine

Engerix B 1mL IM (deltoid) or HB Vax II 1mL IM (deltoid).

Will need 2 further injections to complete the course.

Hep. B Immunoglobulin (HBIG)

Hepatect CP (0.16-0.20mL/kg)
Infuse IV at rate of 0.1mL/kg/hr for 10 minutes.

If well tolerated, gradually increase to a max of 1mL/kg/hr.

PEP FOR HEPATITIS C VIRUS

PEP for hepatitis C virus is not available. Regular monitoring in follow up period could show seroconversion. In this case early referral to ID/hepatology is warranted for consideration of early treatment. The estimated risk of transmission in healthcare workers exposed to HCV-infected blood is 1-3%.

REFERENCES

1. Sonder GJ, *et al*. Prophylaxis and follow-up after possible exposure to HIV, hepatitis B virus, and hepatitis C virus outside hospital: evaluation of policy 2000-3. BMJ 2005;330:825-829

2. UK Guideline for the use of post exposure prophylaxis for HIV following sexual exposure. Int J STD& AIDS 2006 17:81-92

3. David Henderson. Managing Occupational Risks for Hepatitis C transmission in the Health Care Setting Clin Micro Rev July 2003: 546-568

4. Guidelines for the Emergency Management of Injuries (including needlesticks and sharps injuries, sexual exposure and human bites) where there is a risk of transmission of bloodborne viruses and other infectious diseases. HPSC publication. September 2012. Available at: http://www.hpsc.ie/hpsc/A-Z/EMIToolkit/EMIToolkit.pdf

APPENDIX 1: PEP Proforma

Affix patient addressograph here:	**DATE of referral:** *HANDWRITE patient phone number:*

Dear Dr Jackson / Prof Horgan,
PLEASE SEE THIS PATIENT IN THE NEXT ID CLINIC.
Exposure type/decription:

Date and time of exposure:
Hours since exposure:

SIGNED: **Print name:** **Contact details:**

Status of SOURCE person (if known):	HIV status:	Known or perceived risks/concerns relating to source patient:
	Hep B status:	
	Hep C status:	
PEP management:	HIV: Hep B: Other:	

Checklist: Baseline tests: HIV, HepBsAg, HepBcAb, Hep C Ab ☐
FBC, U+E, LFT ☐
Pregnancy test if female ☐
Syphilis if risk involved is a sexual exposure ☐
Tetanus policy followed ☐
Hepatitis B vaccination (unless immune) ☐
Has protocol for hepatitis B and HIV PEP been followed? ☐
Advice given to use condoms for the window period ☐
Emergency contraception if indicated ☐
Called ID CNS (087 6996272) to leave voicemail ☐
Patient informed regarding clinic appointment within week ☐
Patient given phone number/contact details of ID specialist nurse ☐
Information leaflet given to patient ☐

Relevant medical history and/or any other comments:

APPENDIX 2: Patient Information Leaflet

Introduction

This leaflet has been written to give you some basic information about Post Exposure Prophylaxis (PEP) for HIV.

What is HIV?

Human Immunodeficiency Virus (HIV) is a virus that attacks the immune system. Although it isa treatable infection, once infected you have the infection for life. It can be passed on by exposure to infected blood or other infected body fluids e.g. semen. We test for HIV by doing a blood test.

If I have been exposed to HIV, what is the chance that I will become infected with HIV?

This is very difficult to answer and depends on:

1) the type of exposure

2) the chance the source/person is HIV positive.

Overall the risk of infection is low, but certain exposures may carry a higher risk of infection. Even if you have had definite exposure to HIV, this does NOT mean that you will definitely get infected. e.g. the risk of HIV transmission following a needle stick injury from a known HIV positive person is approximated at about 3 infections per 1000 people exposed. PEP further reduces this risk.

What is Post Exposure Prophylaxis (PEP)?

PEP is the term we use for taking "anti- HIV" medication to reduce your chances of becoming infected with HIV. It is only useful in certain circumstances. It has been shown to prevent most (but not all) people becoming infected with HIV. The tablets work best if taken immediately after the exposure. There is no strong evidence for its use beyond 72 hours post exposure.

What does PEP treatment involve?

Your doctor will decide what "anti HIV" tablets you should take and will give you clear instructions on how to take them. You may be seen directly by a specialist who will explain this to you. Or you may be issued a "7 day starter pack" from the Emergency Department containing enough PEP until you are seen by a specialist. You should NOT run out of medication. Usually PEP is taken for a 28 day course and then stopped. During this time you will be seen for regular blood tests to check for side effects. Once you have finished your PEP you will get further appointments for follow up blood tests to check for HIV and other blood borne infections.

Part of the assessment and follow up care is to offer protection against Hepatitis B, and advice regarding Hepatitis C and general sexual health.

What happens if I am Pregnant?
You can still take PEP if you are pregnant, but you must tell the Doctor if you are pregnant or think you are pregnant, as the HIV drugs that you are offered may be different.

What if I am taking other medication?
There is a possibility that other medication may affect or be affected by PEP. It is very important to tell the Doctor if you are taking other medication (including "over the counter" and "herbal" medicines). They will check if these are ok to take with PEP.

Side effects of PEP medication

Side effects include:

- Fatigue
- Nausea/ vomiting
- Diarrhoea
- Feeling bloated
- Abdominal cramps
- Difficulty sleeping
- Abnormal liver blood tests
- Abnormal kidney blood tests
- Skin rash

Please note
This is only a brief account of the side effects and refer to the medication package for further specific information

If you suffer from any of these side effects you should tell the doctor who might be able to offer treatment to help.

What do I do if I miss a dose?
Take the missed dose immediately, and then take the next dose at the normal time. If you don't remember until the next dose is almost due don't take extra doses, just carry on as normal.

Who will look after me whilst I am taking PEP?
Once you have started taking PEP you will be seen either by your Occupational Health Department or local HIV specialist. They will monitor you while you are taking PEP, arrange your blood tests, and offer support. The service, including medication, is free of charge.