

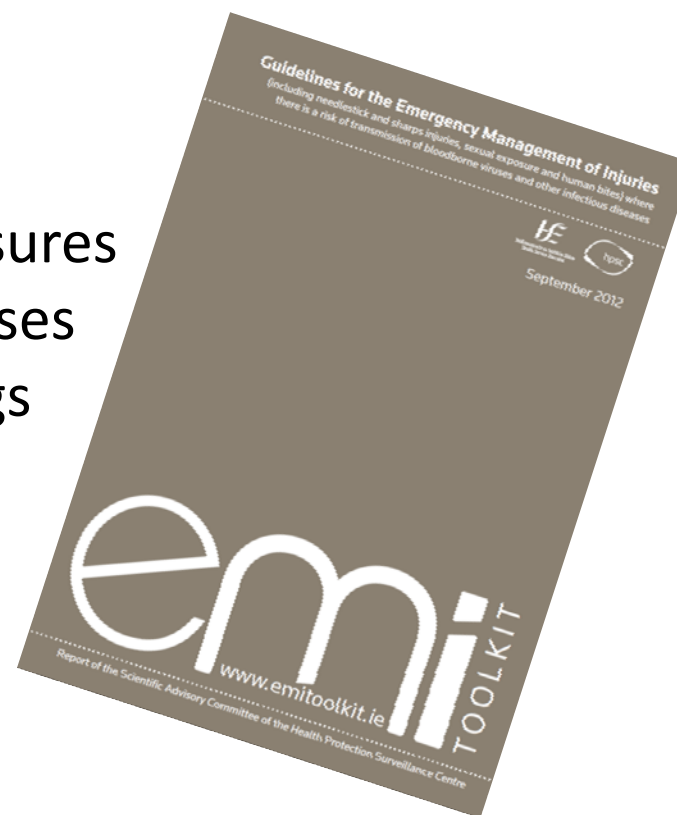


Dr Lelia Thornton
Health Protection Surveillance Centre
National PEP Conference 19 April 2013



Standardised guidelines on the management of injuries

- such as needlesticks, bites, sexual exposures
- where there is a risk of bloodborne viruses
- that could be used in all relevant settings
- based on best available evidence and expert opinion





Garda HIV infection 'as likely as asteroid strike'

Ray Managh

THE risk of a garda contracting diseases from infected drug addicts is as likely as being struck by an asteroid, a High Court judge was told in a test case to define the real risk in 'spit and bite' incidents.

Ms Justice Mary Irvine said the way to allay garda fears of catching Hepatitis or HIV infection was through education.

The State has paid out more than €30m in the past two years for psychological distress and other injuries suffered by gardai on duty.

Judge Irvine, in a judgment on three "fear of disease" test claims, said over-testing by doctors and the imposition of sex restrictions often caused unnecessary anxiety. The risk of being killed driving was much greater than the risk of contracting HIV or Hep C after an assault.

A search of medical literature produced only three cases where HIV had been transmitted by a bite.

Yesterday, she made awards in the three cases of €6,000, €7,000 and €15,000 respectively, saying the gardai had been maliciously assaulted. One had been spat upon and the other two bitten.



Justice Irvine, High Court, 2010

(in the matter of An Garda Síochána (Compensation) Acts 1941)

“there are a number of factors contributing to the increasing prevalence of fear of disease claims.....

- (i) A lack of up-to date knowledge regarding the HIV and HCV viruses and their susceptibility to treatment;
- (ii) An absence of a real understanding as to the circumstances in which blood testing and/or the imposition of restrictions on unprotected sexual relations are warranted following potential exposure; and
- (iii) A grossly inflated view of the possible risk of transmission of these viruses”



EMI Guidelines Working Group

Public Health Medicine

Dr. Lelia Thornton(Chair)
Dr. Anthony Breslin
Dr. Colín O'hAiseadha

Emergency Medicine

Dr. Tomás Breslin
Dr. Una Kennedy

Infectious Diseases

Dr. Susan Clarke
Dr. Jack Lambert

Infection Prevention & Control Nursing

Ms. Mary Clare Kennedy

Occupational Medicine

Dr. Deirdre Fitzgerald
Dr. Oghenovo Oghuvbu
Dr. Alex Reid

Dentistry

Dr. Tom Feeney

Administrative Secretary

Ms. Aoibheann O'Malley - HPSC

Clinical Microbiology

Dr. Brendan Crowley



Existing protocols/guidelines in Ireland

Differed in:

- **Scope and setting** - Occupational/non-occupational; type of injuries covered, which BBVs
- **Recommendations for recipient BBV testing**
 - which tests,
 - store or test baseline,
 - follow-up tests up to 3/12, 6/12, 12/12,
 - HCV testing at 2, 4, 6 weeks
- **Approach to testing source** – if incompetent or refuses
- **Information about quantifying risk**
- **Recommendations on post-exposure prophylaxis (PEP) for HIV or hepatitis B**



Type of injuries covered

- Needlestick or other sharps
- Sexual exposure
- Human bites
- Exposure of broken skin or mucous membranes

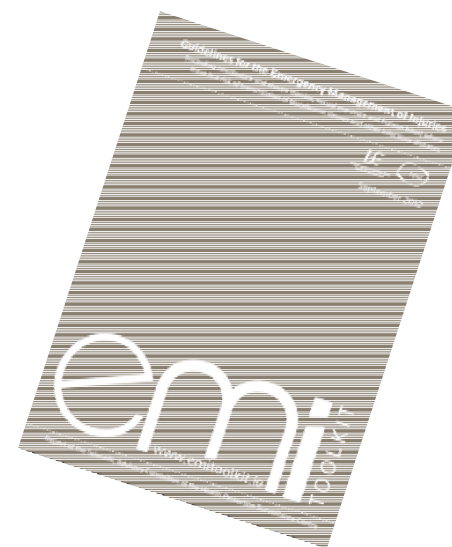




Presentation of guidelines

On-line version

Print version



On-line toolkit www.emitoolkit.ie



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Guidelines for the **Emergency Management of Injuries**
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>> Needlestick injury

>> Mucous membrane exposure

>> Sexual exposure

>> Human bite

>> PEP and PEPSE

>> Forms

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>> Epidemiology of HBV/HCV/HIV

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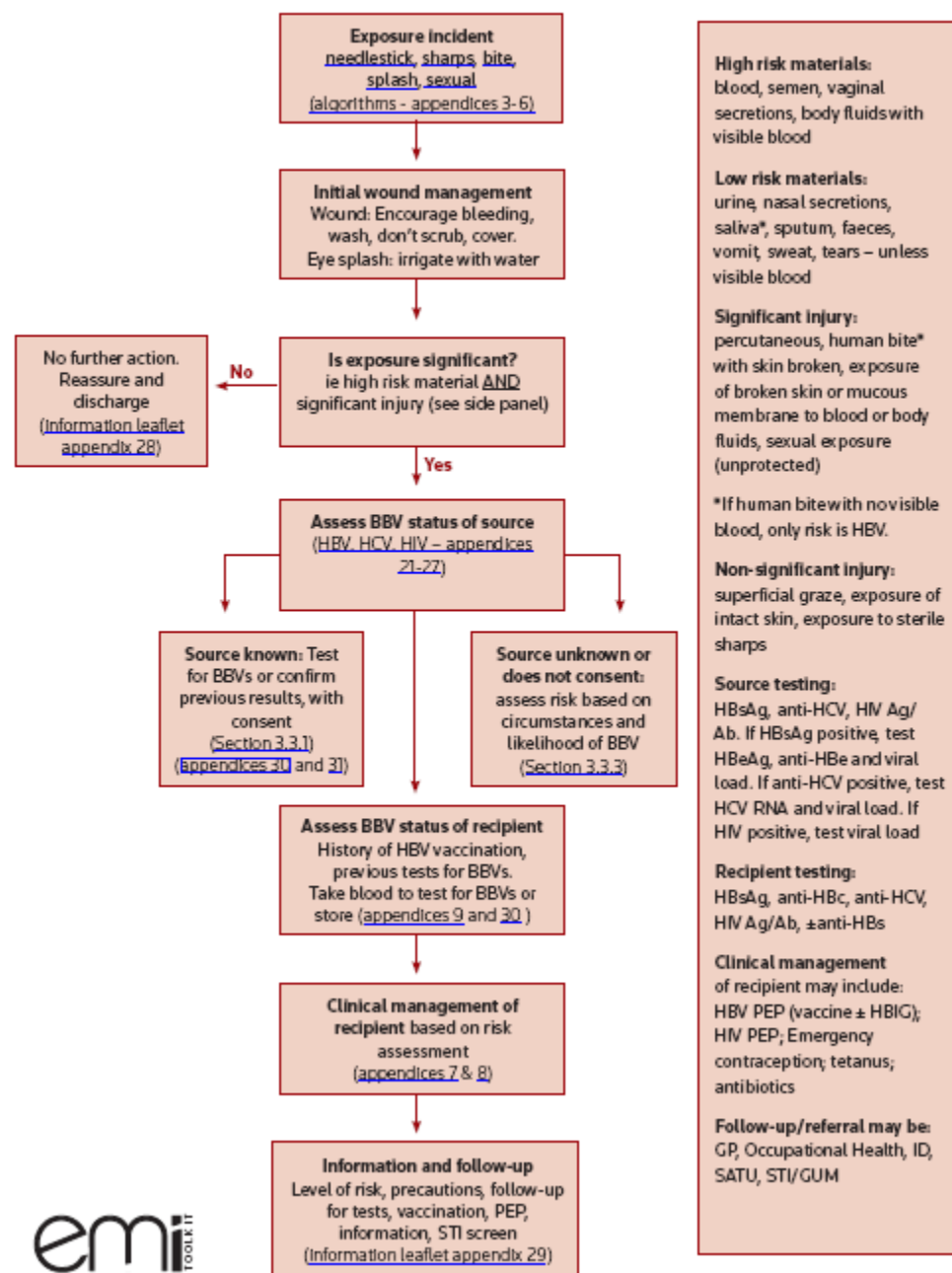
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Management of injuries where there is risk of bloodborne virus (BBV) transmission





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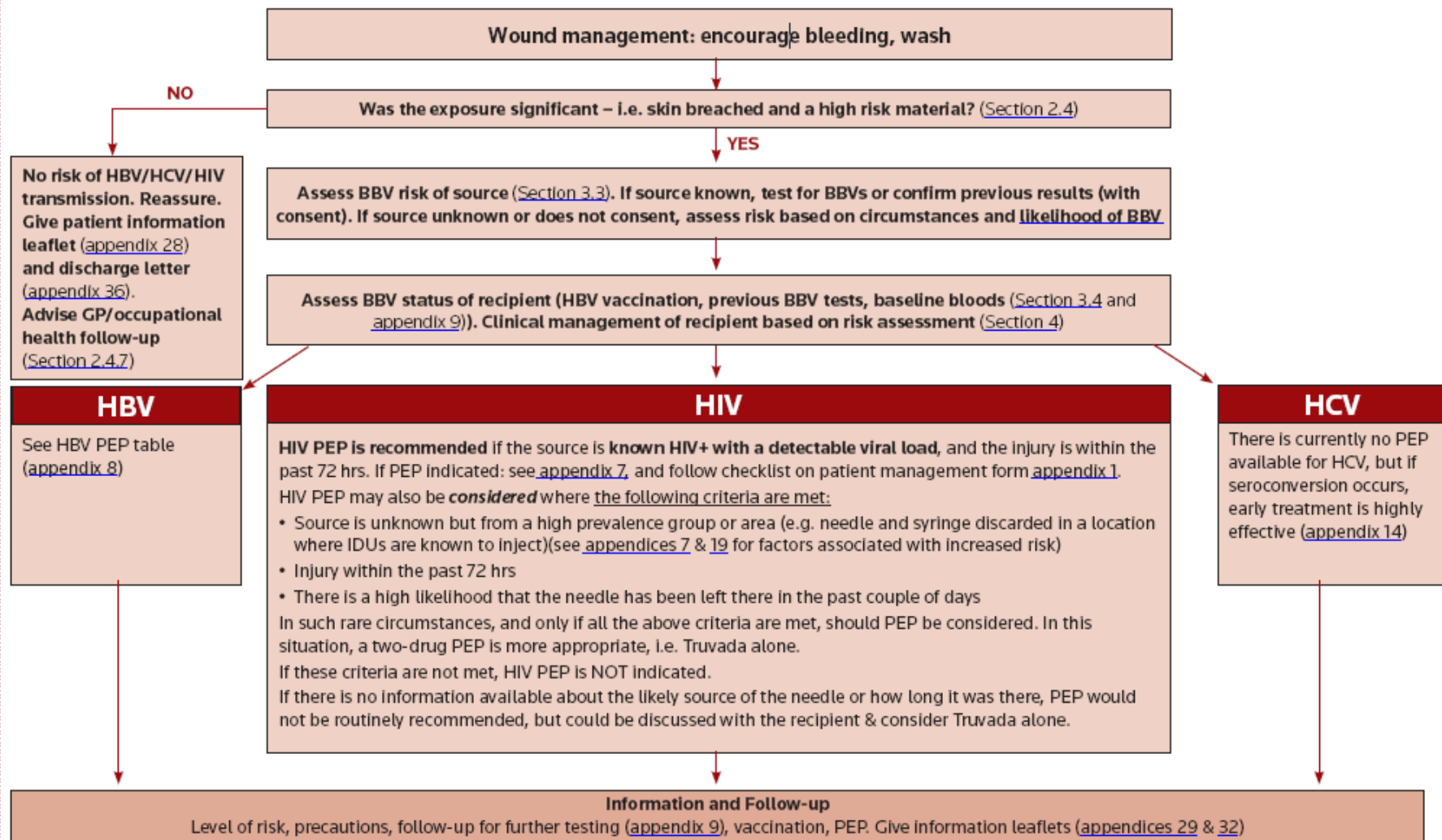
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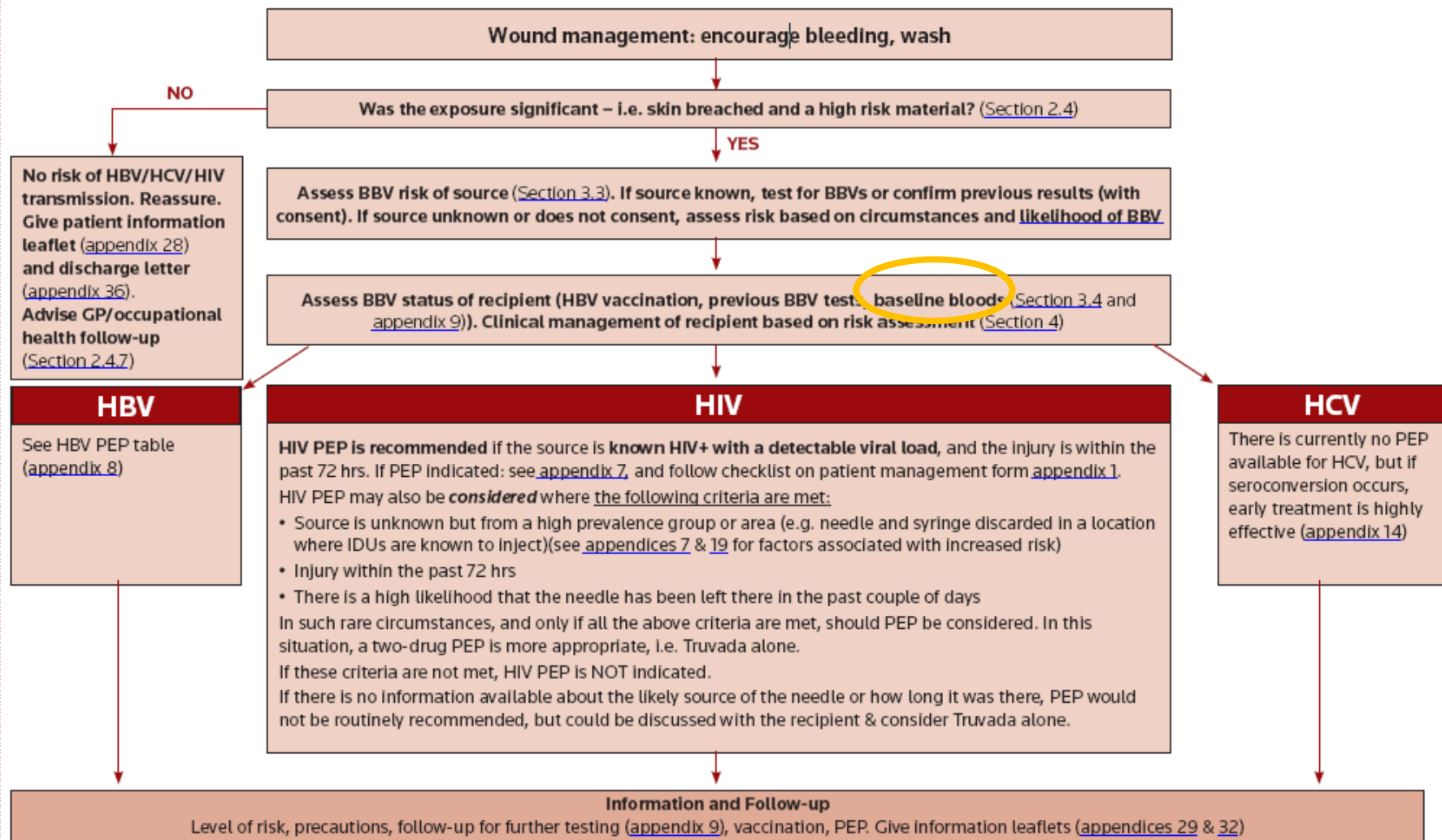
Management of BBV risk following exposure to needlestick/sharps in occupational (appendix 17) or community setting (appendix 19)

Complete patient management form (appendix 1)



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

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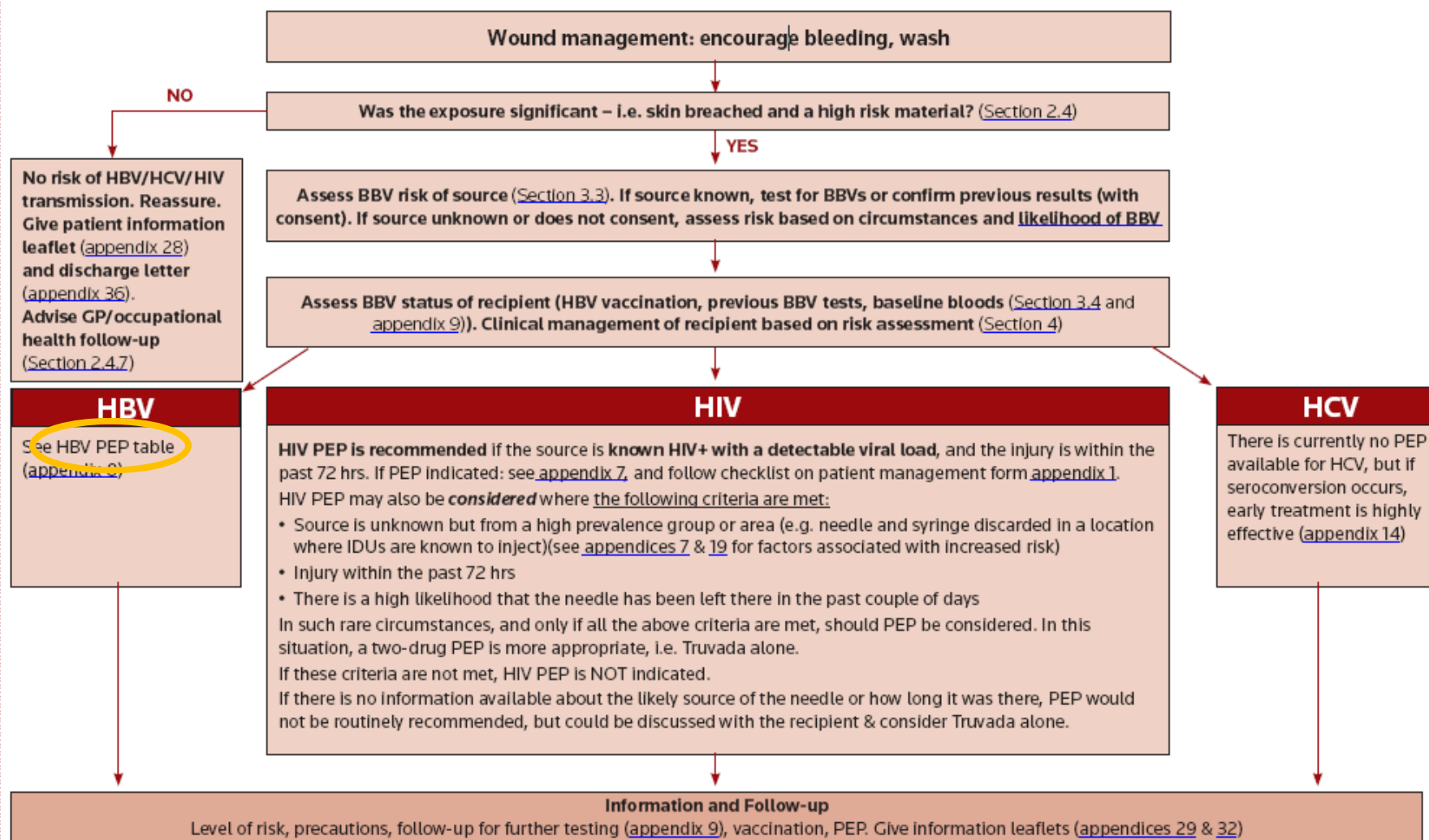


BBV testing of recipient where a significant exposure has occurred

| Time of test | Status of source | |
|------------------|--|---|
| | 1. BBV status unknown <u>OR</u> 2. Negative but high-risk <u>OR</u> 3. Positive for HBV, HCV or HIV | Negative for HBV, HCV and HIV <u>AND</u> not high-risk |
| Baseline* | HBsAg [†] Anti-HBc Anti-HCV HIV Ag/Ab | Testing of recipient not required |
| 6 weeks | HBsAg [†] Anti-HCV HCV Ag or RNA HIV Ag/Ab | |
| 3 months | HBsAg [†] Anti-HCV HCV Ag or RNA HIV Ag/Ab [‡] | |

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

Complete patient management form (appendix 1)



Hepatitis B post-exposure prophylaxis

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

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

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

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

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

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

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



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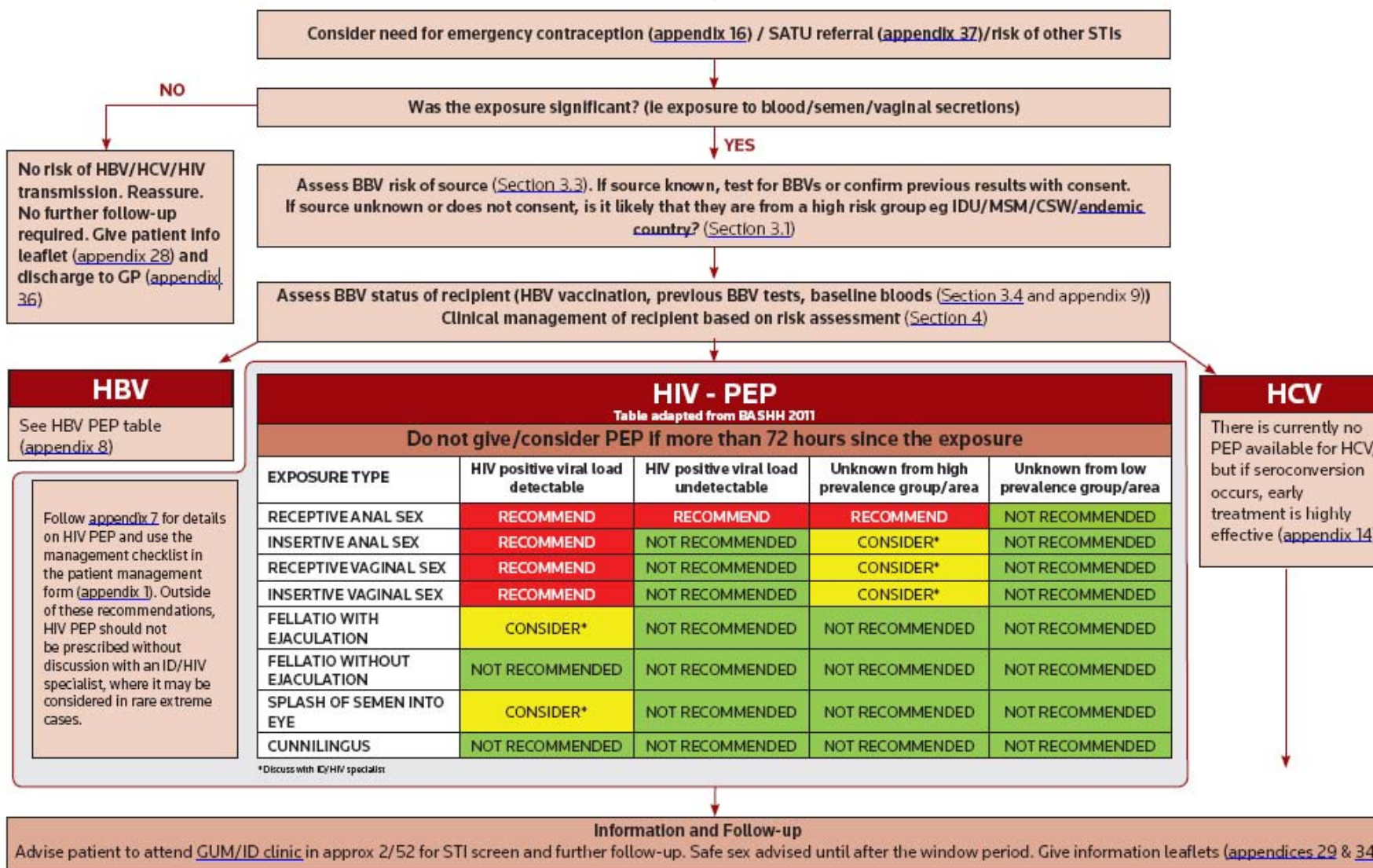
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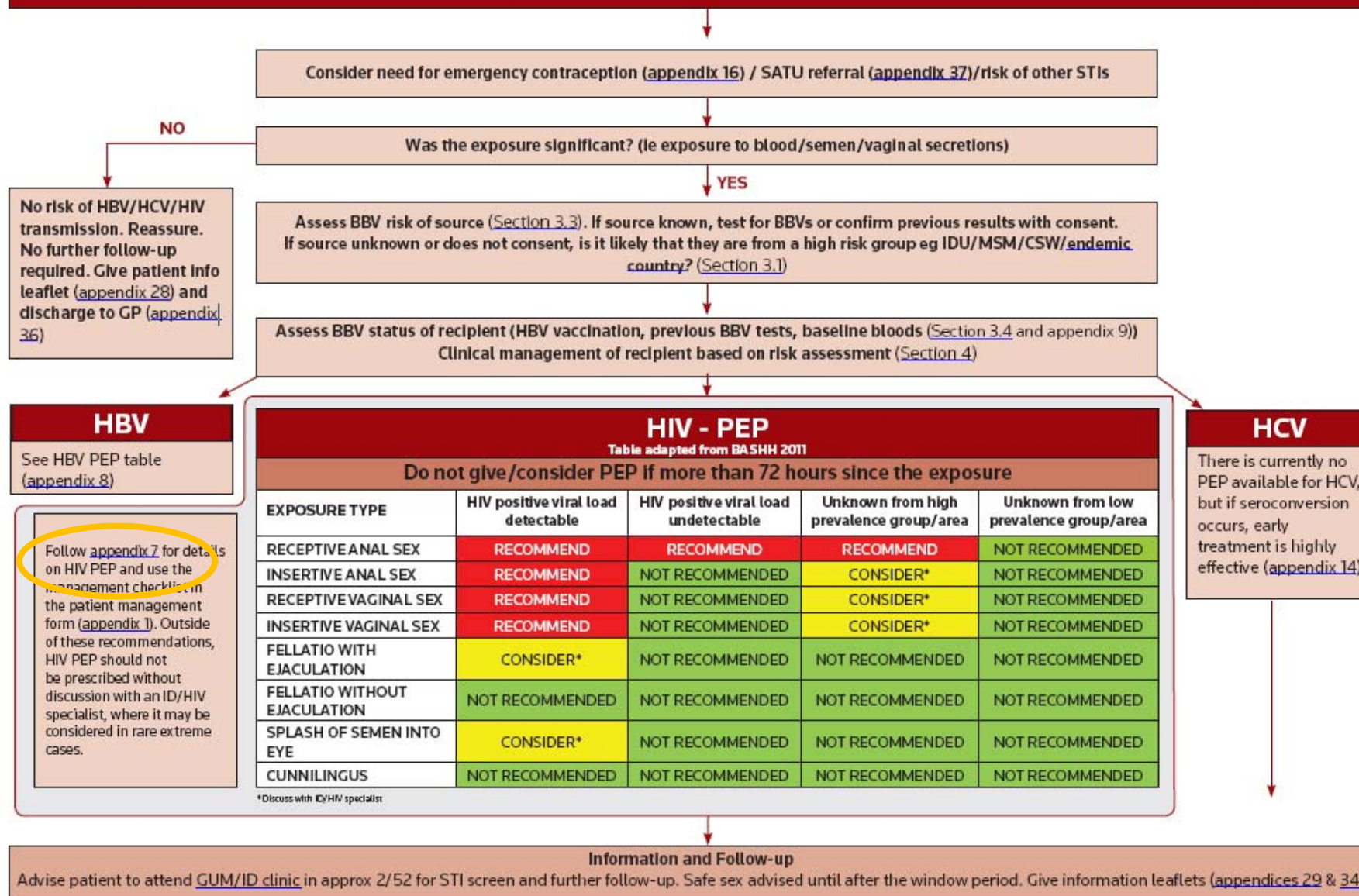
Management of BBV risk following sexual exposure

Complete BBV patient management form (appendix 1)



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HIV POST-EXPOSURE PROPHYLAXIS (PEP)

Key points

1. Only consider PEP if within 72 hours of exposure
2. Assess risk based on type of exposure and what is known about source (consider risk of HBV and HCV also – see relevant [appendices](#))
3. Test source if feasible
4. Discuss with senior doctor in emergency medicine or infectious diseases if unsure how to proceed
5. If PEP indicated:
 - a. Counsel
 - b. Test blood and urine
 - c. Prescribe starter pack
 - d. Arrange [ID clinic appointment](#) before starter pack runs out
 - e. Advise no unprotected sex for 3 months
6. Complete the patient management form ([appendix 1](#)) – it will serve as a checklist

Introduction

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



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Patient Management Form

EMI Guidelines - Appendix 1 Patient management form

Bloodborne Virus Exposure • Patient Management Form

Reporting time: _____ Reporting date: _____
 Doctor name: _____ Doctor signature: _____

RECIPIENT DETAILS

Name: _____ Past Medical History (incl. immunosuppression): _____
 Address: _____
 Gender: M ☐ F ☐ Date of birth: ____/____/____
 MRN: _____
 Tel no.: _____ Mobile: _____
 Occupation: _____
 Work address: _____
 GP name and address and telephone number: _____

ASSESSMENT OF EXPOSURE RISK

Details of injury (date, time, place etc.): _____

Needlestick/sharp injury ☐
 Hollow bore needle ☐ Solid Needle ☐
 Visible blood present ☐
 Device had been directly in source artery or vein ☐
 Other sharp ☐ Describe: _____

Severity of needlestick or sharp injury
 Superficial - source scratch, no blood appeared ☐
 Moderate - penetrated skin and blood appeared ☐
 Deep - puncture, with or without blood appearance ☐

Human bite ☐ Skin breached ☐
 Splash ☐
 Intact skin ☐ Non-intact skin ☐
 Mucous membrane ☐ Eye ☐

Sexual exposure ☐
 Receptive anal ☐ Insertive anal ☐
 Receptive oral ☐ Insertive oral ☐
 Receptive vaginal ☐ Insertive vaginal ☐
 Condom used/ condom intact ☐ Ejaculated ☐

If sexual assault, consider referral to a sexual assault treatment unit or social worker ☐
 Other injury ☐ (describe in "Details of injury" box)

Nature of material (e.g. blood, saliva, semen etc.): _____

If NOT blood, was fluid blood stained? Yes ☐ No ☐

HEALTHCARE EXPOSURES (Consider using local form if applicable)
 Area where exposure occurred: _____
 Was this an exposure prone procedure? Yes ☐ No ☐
 Were gloves worn at the time of the injury? Yes ☐ No ☐

Instrument (if any) which caused the injury: _____
 What was the instrument originally intended for? _____
 Did the instrument have a safety mechanism? Yes ☐ No ☐
 Was the safety mechanism activated? Yes ☐ No ☐

EMI Guidelines - Appendix 1 Patient management form

DECISION

Overall, is exposure significant? (see section 2.4, page 13) Yes ☐ No ☐

If no, no further follow up is required
 Reassured ☐
 Patient information (patient provided) (appendix 29) ☐
 Discharged ☐

If exposure is considered significant, proceed.
 If unsure how to proceed, discuss with senior doctor in the Emergency Department or in Infectious Diseases.

If exposure is considered significant:
 Is source known? Yes ☐ No ☐
 If yes, ID number: _____ e.g. source hospital MRN or laboratory number
 (Health care institution to assign an ID number by which the recipient and source can be confidentially linked)

RECIPIENT MANAGEMENT CHECKLIST

| First aid given | Yes <input type="checkbox"/> No <input type="checkbox"/> (see section 2, page 12) | Treatment record, including PEP | Yes <input type="checkbox"/> |
|--|---|---|------------------------------|
| Recipient bloods taken (appendix 3) | Yes <input type="checkbox"/> No <input type="checkbox"/> | HBV vaccination given (appendices 8 & 11) | <input type="checkbox"/> |
| For testing <input type="checkbox"/> For storage only <input type="checkbox"/> | | HBIG required (appendix 8) | <input type="checkbox"/> |
| Appropriately labeled "Possible BBV exposure - Recipient" | <input type="checkbox"/> | HBIG given | <input type="checkbox"/> |
| HBsAg | Test Date: _____ Result: _____ | HIV PEP offered (appendix 2) | <input type="checkbox"/> |
| Anti-HBc | _____ | HIV PEP accepted (HIV PEP should be discontinued immediately if the source is found to be HIV negative) | <input type="checkbox"/> |
| Anti-HCV | _____ | Considered interactions between PEP and other medication (Consult BNF, pharmacist, www.hiv-druginteractions.org , product insert) | <input type="checkbox"/> |
| HIV Ag/Ab | _____ | HIV PEP information leaflet given (appendix 32) | <input type="checkbox"/> |
| Syphilis (sexual exposures only) | _____ | Baseline bloods taken (FBC, LFTs, Renal, Bone profile) | <input type="checkbox"/> |
| Pregnancy | _____ | Urine/serum for proinflammation (In renal impairment, give first dose of Tenofovir and discuss with an ID consultant. Kaletra can be given) | <input type="checkbox"/> |
| Informed consent received for testing | Yes <input type="checkbox"/> No <input type="checkbox"/> (see Checklist, appendix 30) | Time between exposure and starting HIV PEP _____ hours | |
| Following sexual assault | Yes <input type="checkbox"/> | Number of days of HIV PEP given _____ days | |
| Social worker referral | <input type="checkbox"/> | HIV PEP drugs prescribed (name of drugs) | |
| Sexual assault unit referral | <input type="checkbox"/> | Tetanus vaccine given (appendix 15) | <input type="checkbox"/> |
| Emergency contraception | <input type="checkbox"/> | Tetanus immunoglobulin (TIG) | <input type="checkbox"/> |
| Carda notification if patient agrees | <input type="checkbox"/> | Examined wound for infection | <input type="checkbox"/> |
| | | Antibiotics prescribed | <input type="checkbox"/> |
| | | Note: Record details of medication/ vaccines in patient's chart | |

FOLLOW-UP ARRANGEMENTS

| Precautions advised during follow-up period - 3 months (appendix 29) | Follow-up referral for: (Please use the standard referral forms - appendices 35 & 36) | Name of service |
|--|--|--------------------------|
| Avoid unprotected sexual practices | Test results | _____ |
| Seek expert advice regarding pregnancy or breastfeeding | Further testing (6/52, 3/12) (appendix 32) | _____ |
| Discussed | Vaccinations | _____ |
| Compliance with medication | HIV PEP (urgent, in 3-5 days - appointment to be arranged in ID or HIV clinic, or in the occupational health department (if appropriate)). | _____ |
| Possible adverse reactions and how to manage them | Counselling | _____ |
| No modification to work practices | STI screen | _____ |
| No restrictions to sports | Patient information leaflet regarding significant exposures provided (appendix 29) | <input type="checkbox"/> |
| Importance of advising relevant agency if donating blood, blood products, organ donation, other donation | | |



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Hepatitis B virus: epidemiology and transmission risks

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

Clinical information

Acute infection is clinically recognised in only a small proportion of cases; less 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.¹

Vaccination

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

HIV transmission risk by exposure type

| Exposure | | Risk per exposure (unless otherwise stated) |
|-----------------------------------|--|---|
| Needlestick | Healthcare setting, source patient (serology) known | 0.1-0.36%. ¹³¹⁻¹³³ Increased risk if large gauge needle, hollow needle, deep injury, visible blood on the device, needle was in patient's artery/vein, or if the source patient has AIDS (or terminal illness). Post-exposure prophylaxis reduces transmission by 81%. ¹³² |
| | Healthcare setting, source patient unknown, or unable to test source | Risk assessment required |
| | Community needlestick | Low risk. Risk assessment required. For instance, the risk per intravenous drug injection ranges from 0.63-2.4% ¹³⁴ , but the risk from a community needlestick injury with an unknown source is estimated to be 0.003-0.05% (if local IDU seropositivity is approximately 1%). ⁴⁸ Note: HIV prevalence in IDUs in Ireland is higher - see epidemiology section |
| Mucous membrane exposure to blood | | 0.09% ¹³¹ |
| Intact skin exposure to blood | | No risk ¹³³ |
| Human bite | | Very low risk. ¹³⁸ Risk assessment required. Only risk if blood in the mouth of the biter, and significant injury. No risk if no blood in mouth of biter, and exposure to saliva only. Case report suggests that if source co-infected with HCV, HCV transmission more likely than HIV transmission. ¹⁰⁴ |
| Sexual exposure | Heterosexual exposure (general) | If source on antiretroviral agents - transmission rate = 0 (if viral load < 400 copies/ml) ¹⁵² If source not on anti-retroviral agents, estimated transmission rate 0.0007/coital act (95% CI 0.0006-0.011). ¹⁴⁵ Increased risk if source patient has recently seroconverted ¹⁴⁸ , eg within 2.5 months of seroconversion risk of transmission is estimated to be 0.0082/coital act (95% CI 0.0039-0.015). ¹⁴⁵ Increased risk if STI. ¹⁵⁹ |
| | Receptive vaginal intercourse | 0.1-0.2% per episode. ¹⁴⁹ Increased risk if cervical ectopy, presence of intrauterine device, genital tract trauma ¹⁶⁰ , menstruation ¹⁴⁹ , GUD (in either partner), infectious syphilis, pregnancy. ¹⁴⁸ |
| | Insertive vaginal intercourse | 0.01-0.14% per episode. ^{148, 149} Increased risk if GUD (in either partner), infectious syphilis ¹⁴⁸ , menstruation. ¹⁴⁹ Lack of male circumcision increases risk of HIV transmission to HIV negative male. ¹⁴⁸ |
| | MSM unprotected receptive anal intercourse | 0.1-3% per episode. ¹⁴⁹ Increased risk if ejaculation within the rectum. ^{148, 163} |
| | MSM unprotected insertive anal intercourse | 0.06 (154)- 0.62%. ¹⁵³ Increased risk if uncircumcised. ¹⁶³ |
| | Orogenital contact | Very low risk. ¹⁵⁵ Insertive oral sex 0% risk per act ¹⁴⁸ , and receptive oral sex- 0-0.04% risk of transmission per act ¹⁵⁴ |

Remember

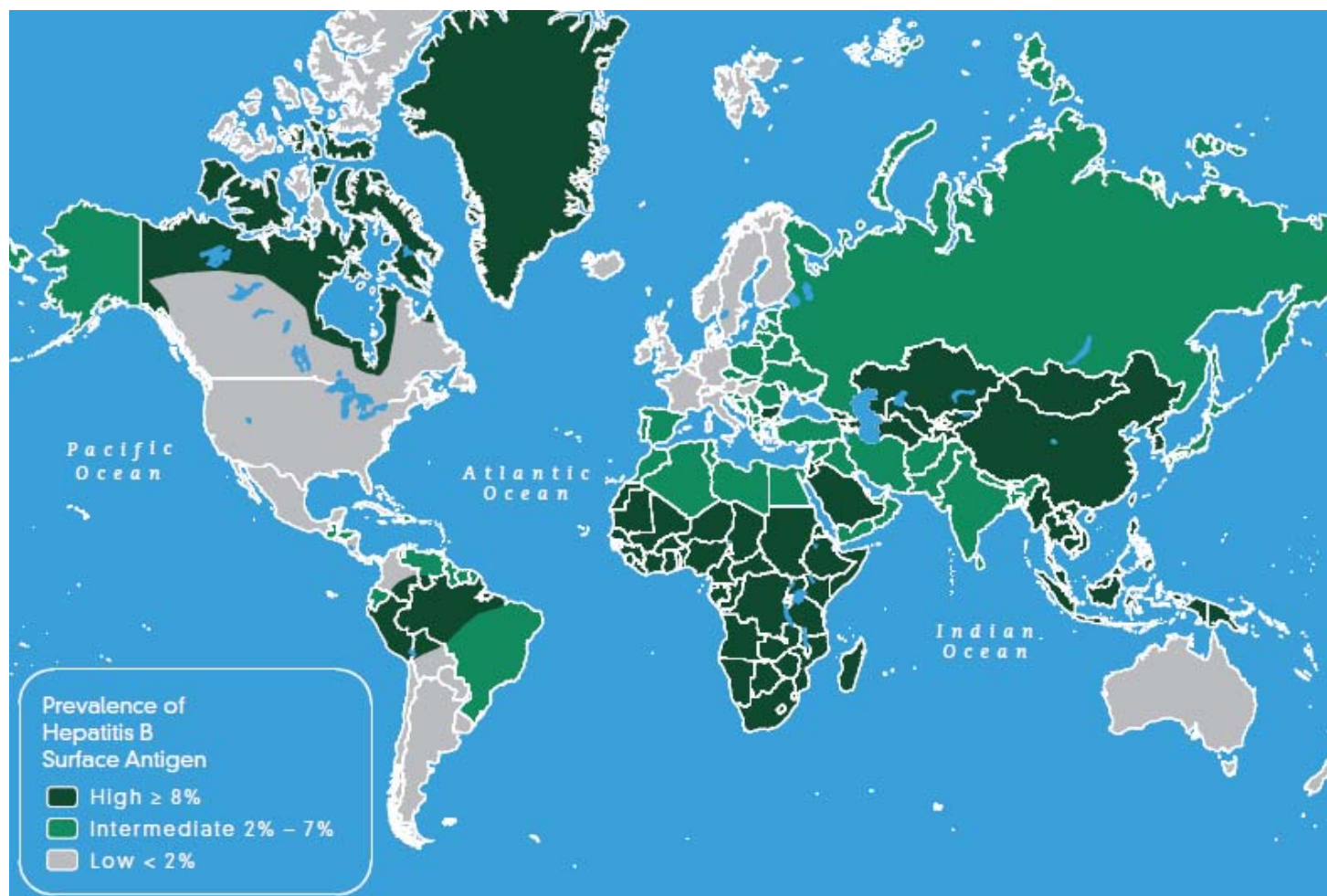
- There are only 5 reported cases of confirmed HIV transmission from a patient to a healthcare worker in the UK¹⁶¹
 - There have been no such transmissions reported since 1999, in the UK
 - Worldwide, there have been only 106 confirmed cases of HIV transmission from a patient to a healthcare worker
 - In 24 of these cases, HIV seroconversion occurred despite use of PEP. In 83% of these, PEP was commenced within 2 hours.

Risk assessment

- Type/ details of injury – as above
- Source status – increased risk with high viral load, recent seroconversion, immunocompromised
- Recipient status – increased risk if immunocompromised, genital tract trauma¹⁴⁹, menstruation¹⁴⁹
- For unknown source, consider where injury occurred – community setting versus hospital setting
 - If in hospital – possible patients in area/ ward
 - If in community, consider prevalence of HIV and of IDU in local population

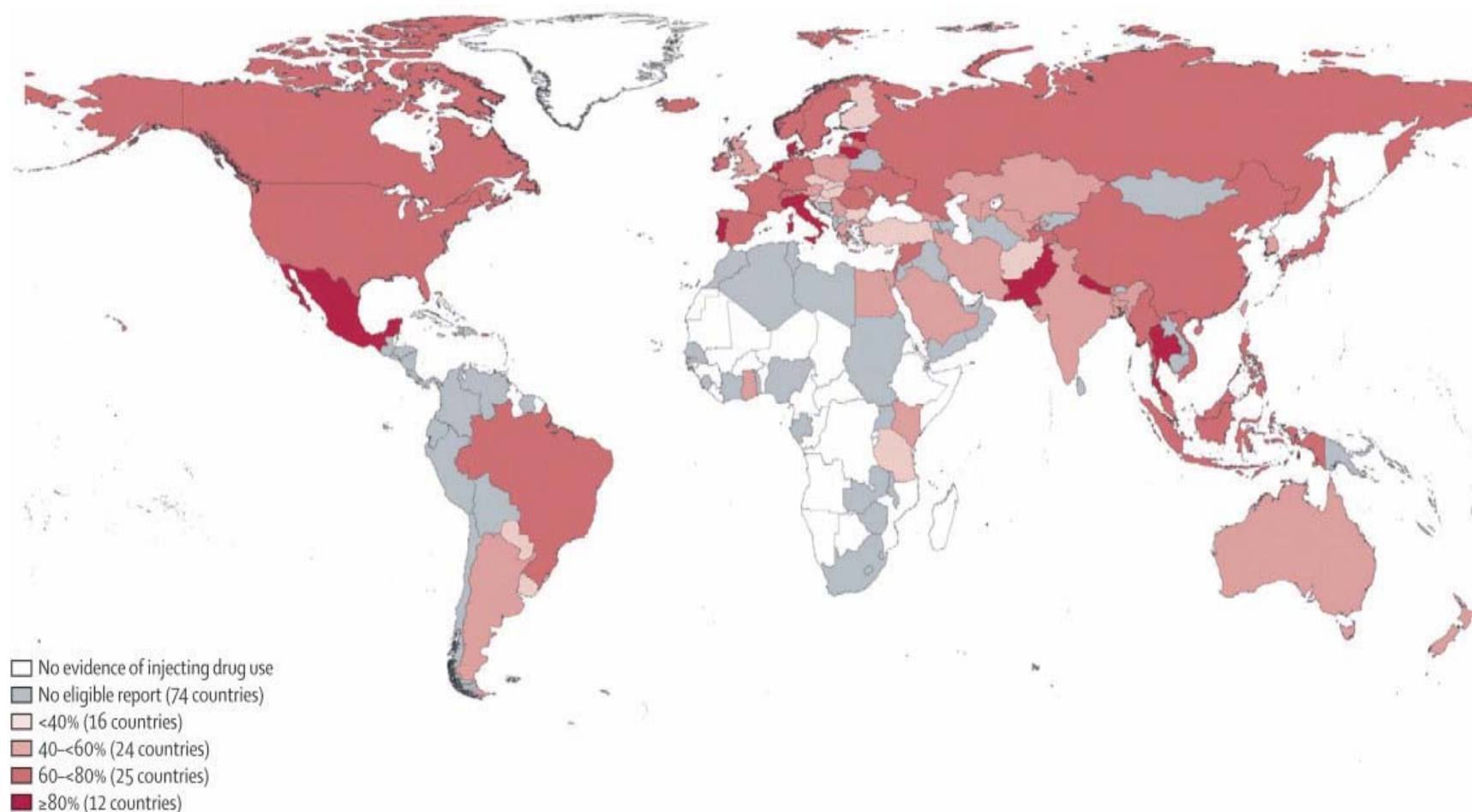


Prevalence of hepatitis B worldwide





Prevalence of anti-hepatitis C among injecting drug users worldwide





Hepatitis B post-exposure prophylaxis

- Hepatitis B vaccine is highly effective in preventing infection after exposure if given within 7 days and preferably within 48 hours
- Hepatitis B immunoglobulin (HBIG) is only indicated where the source is known HBsAg positive, or where the recipient is a known non-responder to HBV vaccine and the source is known to be high risk
- HBIG should ideally be given within 48 hours but not later than 7 days after exposure
- If recipient is a documented responder to vaccine (anti-HBs ≥ 10 mIU/ml) – no need for test or vaccine



Hepatitis C exposure

- No recommended post-exposure prophylaxis for HCV
- Treatment of early infection shown to be successful
- Monitor for evidence of HCV infection
 - Anti-HCV AND Ag or RNA
 - @ 6weeks and 3 months
- If Ag or RNA positive, immediate referral to specialist



HIV post-exposure prophylaxis

- Only if within 72 hours of significant exposure
- Only if known HIV positive or suspected high-risk source
- If source unknown
 - careful risk assessment
 - PEP unlikely to be justified in majority of these
- If PEP indicated, ideally should be started within 1 hour of exposure – 3-5 day starter pack
- Urgent referral to ID/HIV/Occ. Health Specialist
- Duration of PEP is 28 days
- Discontinue immediately if source tests negative



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