

09

Hepatitis B

Vaccine introduced to primary schedule 2008

NOTIFIABLE

In some circumstances, advice in these guidelines may differ from that in the product Summary of Product Characteristics (SmPC). When this occurs, NIAC advises that the recommendations in these guidelines, which are based on current expert advice from NIAC, are followed.

Key Changes

- [Table 9.6](#)

9.1 Introduction

Hepatitis B virus (HBV) is a DNA virus and an important cause of serious liver disease including acute and chronic hepatitis, cirrhosis, and primary hepatocellular carcinoma. People with chronic HBV infection can transmit the infection for many years. Under selective pressure from the host immune response and/or antiviral therapy, viruses with mutations (viral mutants) can emerge as the dominant viral population. A safe and effective vaccine is available for the prevention of HBV infection.

A targeted immunisation programme for those at increased risk of HBV was introduced in 1988 and in 2008, universal childhood vaccination was introduced in Ireland as part of the primary vaccination programme.

Ideally, immunisation should be carried out before the risk of exposure to HBV (pre-exposure prophylaxis) but may follow exposure (post-exposure prophylaxis).

9.2 Epidemiology

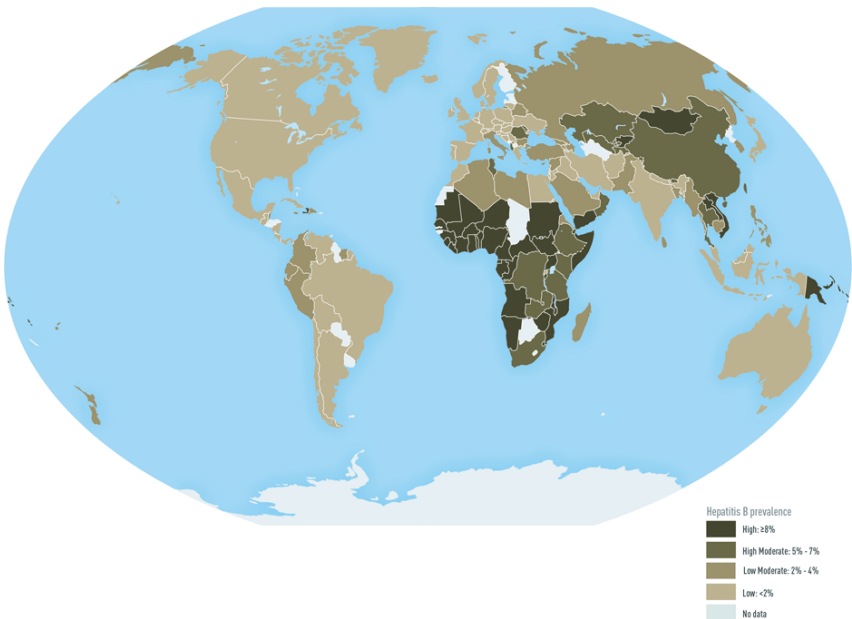
It is estimated that there are 260 million chronically infected cases of HBV worldwide (Figure 9.1).

Hepatitis B prevalence is highest in the WHO Western Pacific and African Regions, where 6.2% and 6.1% of the adult population is infected respectively. In the WHO Eastern Mediterranean Region, the WHO South-East Asia Region and the WHO European Region, an estimated 3.3%, 2.0% and 1.6% of the general population is infected, respectively. In the WHO Region of the Americas, 0.7% of the population is infected.

In Australia, New Zealand, Northern and Western Europe, and North America, the prevalence of chronic HBV infection is low (<2% of the population HBsAg-positive).

Figure 9.1 Geographic distribution of hepatitis B prevalence.

Source: Schweitzer A, et al (2015).



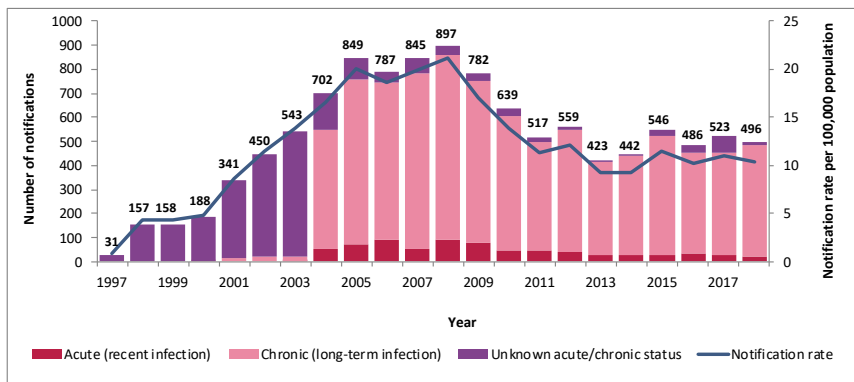
The prevalence of HBV in Ireland is low (<0.5%). HBV is more prevalent in persons with multiple sex partners, sexual partners and household contacts of infected cases, prisoners, IV drug users, homeless persons, immigrants from countries with moderate or high Hepatitis B endemicity.

Figure 9.2 shows the number of cases of hepatitis B notified annually in Ireland since 1997. There was a dramatic increase in notifications between 1997 and 2008, from 31 to 897 cases, mostly attributed to immigrants to Ireland from HBV endemic countries. The decline in immigration in recent years has contributed to the significant decrease to 496 cases notified in 2018.

Over 90% of hepatitis B notifications in Ireland are chronic cases. The number of acute cases of hepatitis B decreased by 23% in 2018 compared to 2017 and was the lowest number of acute cases reported to date in Ireland. Most acute cases are people born in Ireland, who acquired the infection sexually.

Figure 9.2 Number of hepatitis B notifications by acute/chronic status, and notification rate per 100,000 population in Ireland, 1997-2018

Source: HPSC



Most of the notified cases from 2004-2018 were aged 20-44 years (Figures 9.3 and 9.4).

Figure 9.3 Number of acute cases of hepatitis B notified, by sex and median age, in Ireland, 2004- 2018

Source: HPSC

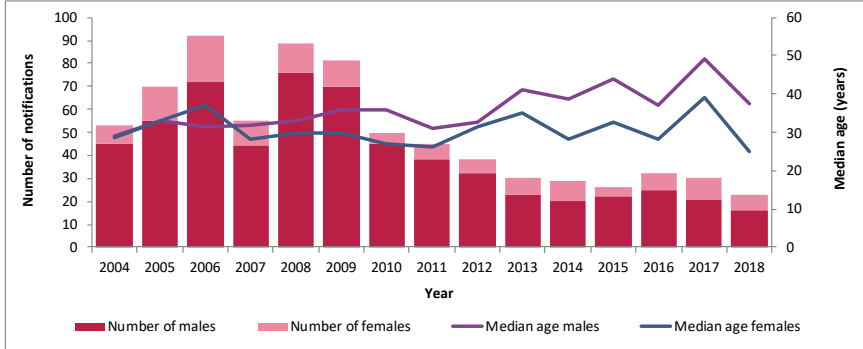
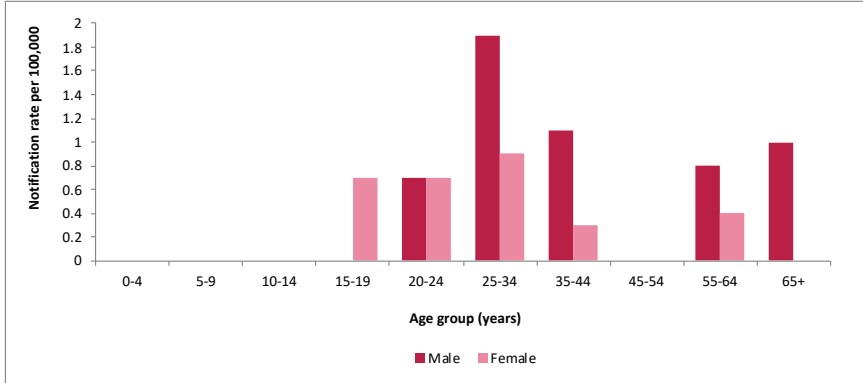


Figure 9.4: Age and sex-specific notification rates/100,000 population for acute cases of hepatitis B in Ireland, 2018

Source HPSC



9.2.1 Transmission

HBV has been found in virtually all body secretions and excretions. However, only blood and serum-derived fluids, saliva, semen and vaginal fluids have been shown to be infectious. People with chronic HBV infection are the primary reservoirs of infection and can be highly infectious. The detection of Hepatitis B e antigen (HBeAg) indicates significant viral replication. However, high viral loads can occur in those who are HBeAg negative but are infected with mutant HBV.

HBV can survive in the environment for ≥ 1 week. Transmission mainly occurs by:

- i. Sexual contact, including vaginal, oral and anal intercourse. The risk of transmission is increased in the presence of other sexually transmitted infections.
- ii. Percutaneous exposures e.g. sharing equipment used by injecting drug users (IDUs), dialysis, non-sterile glucometer equipment, sharing personal care items such as toothbrushes and razors, needlestick injuries, ear-piercing and tattooing.
- iii. Perinatal transmission. The risk of an infant acquiring HBV perinatally from an infected mother 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. However, high viral loads can occur in those who are HBeAg negative but are infected with mutant HBV. Perinatal transmission usually occurs from blood exposure during labour and delivery. *In utero* transmission of HBV causes less than 2% of perinatal infections.
- iv. Close household contact with an HBV infected individual. In household settings, non-sexual transmission may occur. The precise mechanisms of transmission are unknown but may be due to contact of non-intact skin or mucous membranes with blood- containing secretions or saliva.
- v. Transfusion of HBV contaminated blood or blood products. This is rare because of screening of blood donations and viral inactivation of certain blood products.
- vi. Transmission by bite injuries from an HBV infected individual. This is extremely rare.

Patterns of transmission vary according to the prevalence in a country. In high-endemicity countries, infection is predominantly acquired perinatally, or by horizontal transmission among children younger than 5 years. In countries of intermediate endemicity, the pattern of perinatal, childhood and adult infection is mixed and nosocomial infection may be important. In low-endemicity countries, the majority of infections are acquired by sexual transmission or sharing blood-contaminated needles.

9.3 Effects of Hepatitis B

The incubation period is 60-90 days (range 45 -180), depending on the mode of transmission and the HBV viral load of the infecting material. Clinical manifestations depend on the patient's age at infection. In general, the frequency of clinical disease increases with age, whereas the percentage progressing to chronic infection decreases.

Most acute infections are sub-clinical or present with an influenza like illness. In patients with clinical illness, the onset is usually insidious, with tiredness, anorexia, vague abdominal discomfort, nausea and vomiting, and sometimes arthralgia and rash. Jaundice occurs in approximately 10% of young children and in 30-50% of adults. Acute HBV infection may occasionally lead to fulminating fatal hepatic necrosis.

Chronic infection, defined as the presence of HBsAg in the serum for at least 6 months, occurs in more than 90% of those infected perinatally. This decreases to 20-50% in children infected between 1 and 5 years of age. Between 2-10% of infected immunocompetent adults become chronically infected. The risk of chronic infection is greater for immunocompromised individuals.

Approximately 20-25% of those with chronic HBV infection develop progressive liver disease leading to fibrosis, cirrhosis and decompensated liver disease, and are at increased risk of developing hepatocellular carcinoma. HBV causes 60-80% of primary liver cancers.

9.4 Hepatitis B vaccines

Hepatitis B vaccines contain recombinant HBsAg derived from yeast cells, adsorbed onto aluminium hydroxide or monophosphoryl lipid A adjuvant. Hepatitis B vaccines do not contain live organisms and therefore cannot cause HBV infection. The vaccine is 80 to 100% effective in preventing infection or clinical hepatitis in those who receive a complete course of vaccine.

Up to 15% of adults have a poor or no response to three doses of vaccine. Poor response is associated with age over 40 years, male gender, obesity, and smoking. Lower seroconversion rates have been reported in those with alcohol addiction, particularly those with advanced liver disease. Patients who are immunosuppressed or have chronic renal failure may respond less well and may require larger or extra doses of hepatitis B vaccine ([section 9.5.2](#)).

Between 90%-100% of vaccinated persons who develop anti-HBs concentrations ≥ 10 mIU/ml after a primary series are protected from significant HBV infection for at least 20 years and probably longer.

An up-to-date list of licensed vaccines can be accessed on the HPRA website www.hpra.ie

A list of the vaccines currently available from the National Cold Chain Service can be found at www.immunisation.ie

Hepatitis B containing vaccines must be kept refrigerated at $+2^{\circ}$ to $+8^{\circ}$ C and protected from light. If a vaccine has been frozen it should not be used.

9.4.1 Dose, schedule and route of administration

The dose is 0.5 ml or 1ml by IM injection into the anterolateral thigh or deltoid region.

Licensed vaccines contain different amounts of antigen. The recommended dosage should be adhered to (see SmPCs). Specific vaccines are authorised for use in adult patients with chronic renal failure and may be considered for other immunosuppressed adults.

A combined vaccine containing Hepatitis A and Hepatitis B vaccines (Twinrix®) may be used when protection against both HAV and HBV is required

i. Primary vaccination

The primary course in infants consists of three injections at 2, 4 and 6 months of age as part of the 6 in 1 vaccine.

ii. Vaccination of children and adults (Table 9.1)

Three doses at 0, 1 month and 6 months.

The recommended hepatitis B vaccination course requires 3 or 4 doses.

However, a two dose course of Engerix B® 20mcg, given at 0 and 6 months, is acceptable in those aged 11-15 years. The two dose schedule should only be used when there is a low risk of HBV infection, and when compliance with the complete vaccination course can be assured.

Accelerated schedules (e.g. 0, 1 and 2 months; 0, 7 and 21 days) may be used if rapid or very rapid protection is required for those at immediate risk or when compliance with the basic schedule is difficult to achieve. **These three doses should be followed by a dose at 12 months to complete the course.**

Table 9.1 Dose and schedule of Hepatitis B vaccines by age (not including the 6 in 1 vaccine) See Table 9.2 for Hepatitis B vaccines for chronic kidney disease and dialysis patients

Not all listed vaccines may be available in Ireland

Hepatitis B				
Age (years)	Vaccine	Dose	Volume	Schedule (months)
0-≤15	Engerix B paediatric®	10mcg	0.5ml	0,1,6 or 0,1,2,12 ¹
11-≤15	Engerix B®	20mcg	1ml	0, 6 ²
0-≤15	HBVAXPRO5®	5mcg	0.5ml	0,1,6 0,1,2,12 ¹
≥16	Engerix B®	20mcg	1ml	0,1,6 0,1,2,12 ¹ 0,7,21 days ³ + 12 months
≥16	HBVAXPRO10®	10mcg	1ml	0,1,6 0,1,2,12 ¹
Hepatitis A and B				
Age	Vaccine	Dose HAV/HBV	Volume	Schedules
≥16	Twinrix®	720IU/20mcg	1ml	0,1,6 0,7,21 days ³ + 12 months

¹ When rapid protection is required

² Use only for age 11-15 years when there is a low risk of hepatitis B infection and when completion of the two- dose vaccination course can be assured

³ When very rapid protection is required

Interrupted vaccine schedule

If a hepatitis B vaccine schedule is interrupted it does not need to be repeated.

If the schedule is delayed after the first dose, the second dose should be given as soon as possible, and the second and third doses should be separated by at least eight weeks.

If only the third dose has been delayed, it should be given as soon as possible.

iii. Vaccination of chronic kidney disease, pre dialysis and pre renal transplant patients

Fifty to 60% of those with end stage kidney disease develop antibodies following hepatitis B (HBV) vaccination. Increased response rates have been reported in vaccines specially formulated for use in patients with chronic kidney disease (CKD). Those predicted to require renal transplant, should receive HBV vaccine before dialysis or transplant. All patients on dialysis should be given HBV vaccination as soon as possible.

Children should have received HBV as part of the primary immunisation series. Anti-HBs levels should be checked and a full course administered (as per Table 9.2) if <10 mIU/ml. Based on adult experience, vaccination with a higher dosage of antigen (2 doses of Engerix Paediatric® 10mcg) may improve the immune response (Table 9.2). Serological testing is recommended two months following vaccination.

Three vaccines are licensed for patients with CKD, including pre-dialysis and dialysis patients. All are adjuvant adsorbed recombinant DNA vaccines. Fendrix® is indicated in adolescents and adults from the age of 15 years onwards and Engerix B® and HBVAXPRO 40® are indicated from 16 years of age (Table 9.2). When feasible, the same manufacturer's vaccines should be used to complete the series.

When indicated, the dose of Engerix B® and HBVAXPRO® 10 recommended for those with CKD is twice the **volume** recommended for those with normal kidney function i.e.

0.5ml in each deltoid (total 1ml) for those aged ≤15 years

1ml in each deltoid (total 2ml) for those aged ≥16 years.

This does not apply to Fendrix®, which is formulated for those with CKD.

There is no information on the use of Twinrix® in CKD.

Table 9.2 Hepatitis B vaccines for chronic kidney disease, pre-dialysis, and pre transplant patients

Age (years)	Vaccine	Dose	Schedule (months)
0-≤15	Engerix B Paediatric® or HBVAXPRO 5®	0.5ml at 2 sites	0, 1, 6 or 0, 1, 2, 12 ¹
≥15	Fendrix®	0.5 ml	0, 1, 2, 6
≥16	Engerix B® 1ml at 2 sites	1ml at 2 sites	0, 1, 2, 6 ²
	HBVAXPRO 40®	1ml	0, 1, 6

¹ Accelerated course

² If Fendrix® or HBVXPRO40® are not available, Engerix B® 1ml at 2 sites may be given to those aged >15 years to complete a course, giving a total of 4 doses.

9.4.3 Vaccine interchangeability

In general, different hepatitis B vaccines can be used to complete a primary immunisation course or as a booster dose. However, Fendrix® is NOT interchangeable with any other hepatitis B vaccine for the primary course but may be used as a booster dose.

9.5 Pre-exposure prophylaxis recommendations

Pre-exposure immunisation with hepatitis B vaccine is the most effective means of preventing HBV transmission. Non-responders at risk of HBV exposure need to report promptly any inoculation injury, as passive prophylaxis with specific immunoglobulin may be required.

9.5.1 Primary immunisation

Three doses given at 2, 4 and 6 months as part of a 6 in 1 vaccine (DTaP/IPV/Hib/Hep B).

9.5.2 At risk groups

Acceptable evidence of immunity against hepatitis B is

- Written documentation of a completed course of hepatitis B vaccine. If written documentation is not available, a reliable verbal history can be accepted.

and

- Laboratory evidence of immunity

An anti-HBs of 10 mIU/mL or greater is a correlate of vaccine-induced protection only for those who have completed a hepatitis B vaccination series.

Persons who cannot provide written documentation of a complete hepatitis B vaccination series should complete the series and then be tested for anti-HBs one to two months after the final dose.

The following are at increased risk of HBV infection and should receive hepatitis B vaccine if non-immune:

- *Persons with occupational risk of exposure to blood or blood-contaminated environments*
 - Doctors, nurses, dentists, midwives, laboratory staff, mortuary technicians, ambulance personnel, cleaning staff, porters, medical, nursing and dental students, other healthcare professionals.
 - Staff and carers in centres for those with learning disability (including day-care facilities, special schools and other centres).
 - Prison staff in regular contact with prisoners.
 - Security and emergency services personnel
 - Members of An Garda Síochána
 - Members of the fire service
 - Members of the armed forces
 - Any other workers who may be exposed to blood injuries.

- *Family and household contacts*
 - Infants born to mothers with acute or chronic HBV infection (section 9.6).
 - Spouses, sexual partners, family, and household contacts of acute cases and individuals with chronic infection. If testing for markers of current or past infection is indicated, this should be done at the same time as the administration of the first dose. Vaccination should not be delayed while waiting for results of the tests. Further doses may not be required in those with evidence of past exposure.
- *Those adopting or fostering children*
 - Vaccination is recommended for families adopting children from countries with a high or intermediate prevalence of HBV. These children should be tested for evidence of current or past HBV infection.

All short-term foster carers and their families who care for children on emergency placements should receive hepatitis B vaccination. Permanent foster carers and their families, who accept a child known to be at high risk of HBV, should also be vaccinated. Hepatitis A vaccination may also be required (Chapter 8).

- *Injecting drug users (IDUs) and their contacts*
 - All IDUs.
 - Household contacts, children and sexual partners of IDUs.
 - Those at risk of progressing to injecting drug use (including those who are currently smoking heroin and/or crack cocaine or heavily dependent amphetamine users).
- *Individuals at high risk due to medical conditions*
 - Those receiving regular transfusions of blood or blood products.
 - Those with chronic kidney disease (CKD). Fifty to 60% of those with end stage kidney disease (ESKD) develop antibodies following hepatitis B (HBV) vaccination. Increased response rates have been reported with vaccines specially formulated for use in patients with CKD.

All those with CKD should receive HBV vaccine before dialysis or transplant. The vaccination series should be started as soon as CKD is recognised and the patient is known to be HBsAg and anti HBs negative.

All unvaccinated patients on dialysis should be given HBV vaccination as soon as possible. The immune response to hepatitis B vaccine may be diminished compared to immunocompetent individuals, and a more rapid decline in anti- HBs can occur ([Section 9.6](#)).

- Those with chronic liver disease, including those with persistent hepatitis C infection.
 - Those who are non-immune and who are likely to become immunocompromised, such as transplant recipients or those receiving immunomodulatory agents.
 - HIV exposed and infected infants. They should be given Hepatitis B vaccine at birth and then continue with the routine childhood schedule.
 - Attendees at clinics for sexually transmitted infections (STIs) and those diagnosed with an STI.
- *People with other risks*
- Children born to parents from high or intermediate endemicity countries
 - Homeless people
 - Immigrants from areas with a high or intermediate prevalence of HBV
 - Individuals who change sexual partner frequently
 - Men who have sex with men (MSM)
 - Male and female sex workers
 - People engaging in anal intercourse
 - Inmates of custodial institutions
 - Tattoo and body piercing artists/practitioners
 - Those travelling to areas with a high or intermediate prevalence of HBV. This includes volunteers and aid workers, children visiting friends and relatives who might require medical care, patients with underlying medical conditions who may require medical treatment while abroad, medical tourists and those likely to be engaging in risky behaviour e.g. unprotected sexual contact, tattoos and piercing
 - Those with learning disability, attending centres such as day- care facilities, special schools and other units.

Booster doses

Booster doses are not routinely required. Anti-HBs titres decline post-vaccination but a rapid anamnestic response develops after exposure to the virus.

For dialysis patients and immunocompromised people at continued risk of infection, the need for booster doses should be assessed by annual anti-HBs testing (Table 9.4), and a booster dose should be given if the anti-HBs level is <10 mIU/mL.

Contraindications

Anaphylaxis to any of the vaccine constituents.

Precautions

Acute severe febrile illness; defer until recovery.

Adverse reactions

Local: Pain and redness at the injection site are common.

General: Fever, rash, malaise and influenza-like symptoms are uncommon

9.6 Post-vaccination testing and management of those at high risk

Testing for immunity after vaccination is recommended only for persons whose subsequent clinical management or occupational risk depends on knowledge of their immune status.

If indicated, anti-HBs testing should be performed 2 months after the last dose of vaccine.

Such persons are

- Healthcare and public safety workers at high risk of exposure to blood or body fluids containing blood. This includes HCWs with direct patient contact, HCWs at risk of needlestick or sharps injury, and laboratory workers who draw or test blood.
- Immunocompromised persons.
- Infants born to HBsAg positive mothers.
- Sex or needle-sharing partners of HBsAg-positive persons.

Post vaccination serology testing is not required for children receiving hepatitis B vaccine as part of the routine primary childhood immunisation schedule, or for those at low-risk.

Table 9.3 Management following post-vaccination testing
(see Table 9.4 for patients on dialysis)

Anti-HBs level	Action required
≥10 mIU/ml	Good response. No further action required
<10 mIU/ml	<p>Non-responder. Test for anti-HBc.¹</p> <p>If anti-HBc negative, give booster dose of the same hepatitis B vaccine²</p> <p>Recheck anti-HBs 2 months later and if anti-HBs remains <10 mIU/ml, give two further doses of the same hepatitis B vaccine (i.e. complete a second course of the same hepatitis B vaccine)</p> <p>Recheck anti-HBs 2 months later and if anti-HBs remains <10 mIU/ml, person is susceptible to HBV³ to HBV.</p>

¹For those who are performing exposure-prone procedures, HBsAg testing should also be carried out.

² If not available, a different hepatitis B vaccine can be used

³ Should be advised about precautions to prevent HBV infection and the need for post exposure prophylaxis for any known or likely exposure to an HBsAg-positive source

For chronic kidney disease, including those on dialysis:

- with anti-HBs <10m IU/ml. 2 months after a high dose vaccine course, a repeated course of vaccination, with a high dose of the same hepatitis B vaccine, is recommended (see Table 9.2). This results in protective anti-HBs titres in ≥50% of previous non-responders
- if there is still no response (anti-HBs <10m IU/ml 2 months after the second course) it is unlikely that there will be benefit from additional vaccines. Persistent non-responders are probably not protected against hepatitis B, and should minimise potential exposure. They should be given hepatitis B immunoglobulin within 72 hours of parenteral or mucosal exposure to hepatitis B virus.

Table 9.4: Management following post-vaccination testing for chronic kidney disease including those on dialysis

Anti HBs (mIU/ml)	Interpretation and management	Follow Up
≥ 10	Good response	Re-check anti-HBs annually. If anti-HBs < 10 mIU/ml, give booster dose of vaccine.
<10	Non-response. Repeat vaccination course (same brand). Check anti-HBs 2 months later: <ul style="list-style-type: none"> • If ≥10 mIU/ml, good response • If < 10 mIU/ml, non-responder 	Test for HBsAg three monthly while on dialysis

9.7 Post-exposure prophylaxis (PEP) recommendations

PEP with hepatitis B vaccine and hepatitis B immunoglobulin (HBIG) or hepatitis B vaccine alone prevents most infections after exposure to HBV. Post-exposure hepatitis B vaccination is highly effective at preventing clinically relevant infection if administered preferably within 48 hours but up to 7 days post-exposure.

When hepatitis B vaccine is used, it must be administered using the accelerated schedule, i.e. 0, 1, 2 and 12 months.

HBIG provides short-term protection (3-6 months).

Dose and route of administration of HBIG

Follow the manufacturer's guidelines and ideally give within 48 hours of exposure but not later than 7 days after exposure. Refer to the HPSC EMI toolkit, [Appendix 13](#).

<https://www.hpsc.ie/a-z/EMIToolkit/appendices/app13.pdf>

i. Babies born to mothers who are HBsAg positive

Perinatal transmission of HBV infection can be prevented in approximately 95% of infants born to HBsAg positive mothers by early active and passive immunoprophylaxis of the infant. All babies born to these mothers should receive hepatitis B vaccine at 0, 2, 4 and 6 months, and HBIG as soon as possible, ideally within 24 hours of birth, but no later than 7 days.

The first dose of monocomponent HepB vaccine should be given within 24 hours of birth. The doses at 2, 4 and 6 months should be given as 6 in 1 vaccine. Arrangements should be made to follow-up the child for subsequent doses of vaccine and testing for anti HBs, HBsAg, and anti-HBc.

Hepatitis B vaccine may not give an adequate immune response in infants weighing less than 2kgs, until they are aged one month or more. However, if a mother is HBsAg positive, her infant should be given hepatitis B vaccine and HBIG at birth irrespective of birth weight, and further doses (as 6-in-1 vaccine) at 2, 4 and 6 months of age.

Infants born to mothers who are HBV infected should be tested after completing hepatitis B immunisation to determine their HBsAg and anti- HBs serology. Testing should be carried out 2 months after the last dose and ≥ 9 months of age, to avoid detection of passive anti-HBs from HBIG.

ii. Household exposure

HBIG and hepatitis B vaccine are recommended for unimmunised infants aged less than 12 months if the mother or primary caregiver has acute HBV infection. Prophylaxis with HBIG is not indicated for other unimmunised household contacts of persons with acute HBV infection unless they have blood exposure to the index patient, such as by sharing of toothbrushes or razors. Such exposures should be managed as are sexual exposures. All household contacts of acute and chronic cases should be given hepatitis B vaccine and screened. They should complete the vaccine course if susceptible.

iii. Sexual exposure

Exposure to acute cases: Sexual partners of individuals suffering from acute hepatitis B and who are seen within one week of last contact should be offered both HBIG and vaccine, unless immune from vaccination or past exposure. Hepatitis B vaccine should be offered even if more than one week has elapsed since contact.

Exposure to chronic cases: Sexual contacts of newly identified chronic cases should be offered vaccine, unless immune from vaccination or past exposure. HBIG should be offered if unprotected sexual contact occurred in the previous week. A risk assessment may be needed depending on whether the contact is a long-term or recent sexual partner.

iv. HCWs and those accidentally exposed to blood or body fluids

Individuals who sustain such injuries should wash the affected area well with soap and water and seek medical advice. The response required in terms of vaccination and/or HBIG will depend on a detailed risk assessment of the source, the vaccination/anti-HBs status of the person exposed, and the type of exposure. Appropriate prophylaxis should be commenced immediately (Table 9.5).

Significant exposure is defined as exposure from which hepatitis B transmission may result e.g.

- Percutaneous exposure to blood or body fluids, e.g. needle stick bleeding or visible skin puncture
- Mucocutaneous exposure to blood or body fluids, e.g. contamination of non- intact skin, conjunctiva or mucous membrane
- Sexual exposure (unprotected oral, vaginal or anal).

9.7.2 Injuries from discarded needles in the community

While these injuries pose less risk than that resulting from a needlestick injury in health-care settings, the perception of risk often results in the necessity for evaluation, testing and counselling of the injured person. HBV can survive in the environment for 1 week or longer.

Management of such injuries includes acute wound care and consideration of the need for prophylactic management. It is advisable to administer a course of hepatitis B vaccine to those susceptible to HBV infection. HBIG is not usually required unless the needle comes from a known hepatitis B positive source and a risk assessment identifies a significant risk of HBV transmission. The likelihood of transmission of other blood-borne viruses such as hepatitis C or HIV is very remote.

Recommendation: a baseline serum specimen from the injured person should be collected and tested if required. Initiate hepatitis B vaccination and test samples at 6 weeks and 3 months (for guidance refer to the Emergency Management of Injuries (EMI) Guidelines (www.emitoolkit.ie)). Test anti-HBs 2 months after completion of the vaccination course.

Testing the needles or syringe contents for evidence of blood borne infection is not indicated.

Interpretation of Hepatitis B results is shown in [Table 9.6](#).

Table 9.5: Hepatitis B post-exposure* prophylaxis (Adapted from the EMI Guidelines www.emitoolkit.ie)

*Needlestick injury/ Bite with breach of skin/ Sexual exposure/ Mucosal exposure to blood or body fluids containing blood

Serology of source	Vaccination status and Management of person exposed				Anti-HBs <10 mIU/ml	Anti-HBs ≥10 mIU/ml
	Unvaccinated	Not fully vaccinated (<3 doses)	Fully vaccinated anti-HBs unknown ¹	Anti-HBs <10 mIU/ml		
HBsAg positive	Give HBIG ² Accelerated ³ vaccine course ¹ Urgent consult to ID/GUM specialist	Test recipient for anti-HBs Consider HBIG ² if <10 mIU/mL Complete vaccine course-Urgent consult to ID/GUM specialist	Test recipient for anti-HBs Consider HBIG ² if <10 mIU/mL Give vaccine dose ⁴ Urgent consult to ID/GUM specialist	Give HBIG plus vaccine dose Urgent ID/GUM referral for alternative vaccination strategy	Consider giving HBV vaccine dose based on risk assessment of severity of injury	
HBV status unknown but potential high risk, i.e. from country of high or intermediate prevalence⁵	Test source if possible. Accelerated ³ vaccine course ⁴	Test the source if possible Complete vaccine dose ⁴	Test source if possible Give vaccine dose ⁴	Test the source if possible Consider HBIG ² Urgent ID/GUM referral for alternative vaccination strategy	No action	
HBV status unknown - normal risk⁶	Accelerated ³ vaccine course ⁴	Complete vaccine course ⁴	Give vaccine dose ⁴	Test source if possible Give vaccine dose Urgent ID/GUM referral for alternative vaccination strategy	No action	
HBsAg negative	Routine vaccine course ⁴	Complete vaccine course ⁴	No action	Routine ID/GUM referral for alternative vaccination strategy	No action	

Where indicated give Hepatitis B vaccine / HBIG within 7 days and preferably within 48 hours

¹ If the recipient was fully vaccinated, no further testing or vaccination is required

² For a bite with no visible blood, risk assess or seek urgent ID specialist advice

³ See section 9.4.1

⁴ Test for anti-HBs 2 months after the final dose of hepatitis B vaccine

⁵ See Figure. 9.1

⁶ Injecting drug users in Ireland have a 2% risk of being HBsAg +ve and are not high risk.

Table 9.6: Interpretation of Hepatitis B serology

HBsAg	HBeAg	Anti-HBe	Anti-HBc IgM	Anti-HBc total	Anti-HBs	Interpretation
Neg	Neg	Neg	Neg	Neg	Neg	Susceptible to HBV
Pos	Pos	Neg	Pos/Neg	Pos/Neg	Neg	Acute HBV infection
Neg	Neg	Neg	Pos	Pos ¹	Neg	Recent HBV infection
Pos	Pos	Neg	Weak Pos/ Neg	Pos	Neg	Chronic HBV infection ²
Pos	Neg	Pos/Neg	Weak Pos/ Neg	Pos	Neg	HBsAg negative chronic HBV infection ³
Neg	Neg	Pos/Neg	Neg	Pos ³	Pos/Neg	Resolved HBV infection
Neg	Neg	Neg	Neg	Neg	Pos	Response to hepatitis B vaccine

¹ Anti-HBc detected in two assays

² Follow up serology required to confirm chronic HBV infection

³ Possible explanations for isolated anti-HBc total are:

- a) Resolving acute infection in the window period before anti-HBs response
- b) Recovery from past HBV infection with persistence of anti-HBc and loss of detectable anti-HBs,
- c) Low level (undetectable) hepatitis B surface antigen (occult hepatitis B infection),
- d) False positive anti-HBc.

Follow up serology required: HBV DNA viral investigations may be required.

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