



## OPERATIONAL DIRECTIVE

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**Subject:** **Hepatitis B Vaccination Program**

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This Operational Directive is designed to advise Department of Health (DOH) staff on policies and procedures relating to the hepatitis B vaccination program and may contain advice that is not appropriate in other circumstances.

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## 1. BACKGROUND

The initial strategy for the control of hepatitis B in Australia commenced in 1998, targeting groups at particular risk of infection for vaccination at birth. In addition to offering vaccine, hepatitis B immunoglobulin (HBIG) was given to the infant if the mother was a hepatitis B carrier. In 1996, the National Health and Medical Research Council (NHMRC) recommended a universal hepatitis B vaccination program for infants and adolescents. The adolescent program commenced in WA in 1998, and the infant program began nationally in 2000. The adolescent program will continue until those immunised for hepatitis B in the childhood program reach pre-adolescence in 2010.

The reason for offering hepatitis B vaccination to pre-adolescent children is to protect them against accidental infection and/or prevent them from becoming infected by the hepatitis B virus later in life. Although most new hepatitis B infections occur in adolescents and young adults because of unsafe sex or unsafe drug-injecting practices, the source remains unknown for many other infections.

## 2. HEPATITIS B

Hepatitis B is an infectious disease of the liver caused by the hepatitis B virus (HBV). About 50% of adults and 10% of children develop symptoms after HBV infection, which can be acute (short-term) or chronic (long-term). After an incubation period of 2 to 6 months, HBV infection usually causes an illness with symptoms that include tiredness, loss of appetite, nausea, weight loss, abdominal discomfort, and jaundice (yellowing of the skin and whites of the eyes and dark-coloured urine). Less common symptoms include fever, arthritis, and rash. About 1 in 100 hospitalised hepatitis B patients die from acute HBV infection.

- **Chronic Hepatitis B Infection**

About 95% of adults infected with HBV make a complete recovery. However, up to 90% of infants and 5% of older children and adults are unable to eliminate the HBV and remain infected for many years even though they are not usually symptomatic. People with chronic HBV infection are called hepatitis B carriers and can infect others with HBV. In Australia, about one person in every 1,000 is a hepatitis B carrier and about 1 in 5 carriers will die prematurely of either cirrhosis (liver failure) or liver cancer.

- **Epidemiology**

About 20 to 50 new cases of HBV infection are reported to the WA Department of Health each year. Most new cases are between 15 and 40 years of age. People from Central or South America, Southern or Eastern Europe, Africa, India, the Middle East, China, South East Asia, the Pacific Islands, and Indigenous Australians have a higher proportion of chronic HBV infection due mainly to maternal-child transmission over many generations.

- **Transmission**

Blood is the most infectious source of HBV, but other body fluids including semen, vaginal secretions, saliva and breast milk can also transmit HBV. Tears, sweat, urine, and faeces do not appear to transmit HBV. Both acute and chronic hepatitis B patients are infectious.

- **Treatment**

There is no effective, specific treatment for acute HBV infection. However, there are some drugs available for the treatment of chronic HBV infection, including alpha-interferon, lamivudine and adefovir.

- **Prevention**

HBV transmission can be prevented by:

- Immunisation,
- Not sharing any drug injecting equipment (e.g. needles, syringes, spoons, tourniquets, and water),
- Not having unprotected sex,
- Not sharing toothbrushes, dental floss, razors, or nail files,
- Demanding sterile equipment for tattooing, ear or body-piercing, acupuncture or electrolysis,
- Immediately cleaning and dressing wounds.

### **3. INFANT HEPATITIS B VACCINATION PROGRAM**

As of the 1 May 2000 every child born was/is eligible for free hepatitis B vaccines. The paediatric formulation of the vaccine should be used. The first dose of hepatitis B vaccine should be given soon after birth (e.g. prior to discharge from the maternity unit), followed by 3 more doses of hepatitis B vaccine (given in combination vaccine Infanrix-Hexa at 2, 4, 6 months of age). A minimum of three doses of hepatitis B vaccine are required to complete hepatitis B immunisation. If one of the 4 scheduled doses of hepatitis B vaccine is missed, a 4<sup>th</sup> dose is not required. Routine booster doses of hepatitis B vaccine are not recommended.

The infant hepatitis B vaccination should be reviewed at the time of the paediatric discharge assessment, and if not already administered, should be discussed and offered before discharge. All vaccinations should be recorded on the Childhood Immunisation Record for parents to keep.

- **High risk newborn children**

Every pregnant woman should be screened for hepatitis B infection. The baby of a hepatitis B carrier (i.e. HBsAg positive) mother should be given both hepatitis B immunoglobulin (100 IU) and a first dose of hepatitis B vaccine as soon as he/she is physiologically stable, preferably within 24 hours of birth. The child should then be given the routine hepatitis B vaccination schedule at birth, 2, 4, and 6 months of age and tested for immunity to hepatitis B (i.e. anti-HBs) 2-3 months after the 3<sup>rd</sup> vaccine dose. This regimen results in seroconversion rates of more than 90% in neonates.

- **Preterm babies**

Preterm babies do not respond as well to hepatitis B-containing vaccines as term babies. Babies born at <32 weeks gestation or < 2000g birth weight should be vaccinated at 0, 2, 4 and 6 months and either:

1. Have a blood test at 7 months of age, with a booster dose of vaccine if the antibody titre is < 10mIU/ml, or
2. Have a booster dose at 12 months of age without measuring the antibody titre

- **Maternity hospitals**

Maternity units should implement policies and procedures to include routine administration of hepatitis B vaccination for newborn children to be given in the recommended time frame.

#### **4. YEAR 7 SCHOOL -BASED HEPATITIS B VACCINATION PROGRAM**

Hepatitis B vaccine is provided free to students in year 7 through the school-based program. This service is delivered in the metropolitan area by either Local Government Authorities (LGAs) or by Child and Adolescent Community Health Services (CACHS). In regional areas, the school-based program is delivered through Population Health Units (PHUs) community nurses. Parents who do not wish their child to be vaccinated at school, or whose child misses the immunisation day at school, can arrange to have their child vaccinated by a local GP. Alternatively, they can attend the Central Immunisation Clinic (Perth), or Community Health Immunisation clinics.

- **Vaccine**

The only vaccine available for the Year 7 Hepatitis B Vaccination Program will be the adult (10 mcg, 1 mL) H-B-VAX II Im hepatitis B vaccine, for which a two dose schedule (0, 4 - 6 months) has been approved for adolescents 11 to 15 years of age. This formulation does not contain thiomersal.

Vaccines are ordered from CSL in the metropolitan area and regional pharmacies in the regional areas (except Pilbara who order direct from CSL). An order form is attached.

CSL vaccine distributors submit all vaccine order data to CDCD.

GPs requesting hepatitis B vaccine for students in Year 7 should complete the attached form and fax to (08) 9388 4820. This information will be recorded in the school-based database.

- **Serology**

Children should not routinely be tested for hepatitis B vaccination immunity (i.e. hepatitis B surface antibody - i.e. anti-HBs) unless they fall into a high risk exposure category for HBV, in which case they should be tested 2 to 3 months following the last dose of hepatitis B vaccine.

#### **5. HOUSEHOLD OR SEXUAL CONTACTS OF HBV CARRIERS**

On receipt of a notification of a hepatitis B case, the local public health nurse (PHN) follows up with the reporting doctor and with the case to discuss household and sexual contacts. All household and sexual contacts of a hepatitis B carrier should be screened for hepatitis B infection. Non-immune household and sexual contacts should be offered free hepatitis B immunisation (and hepatitis B immunoglobulin if significant exposure has occurred). Refer to page 158 of the Immunisation Handbook. Free hepatitis B vaccines, using the attached order form, can be obtained through:

- Regional pharmacy.
- Perth metropolitan area from CDCD, Tel: (08) 9388 4838 Fax: (08) 9388 4820.
- Australian Red Cross Blood Service for HBIG, Tel: (08) 9325 3333.

## 6. HEALTH CARE WORKERS

Health Care Workers are encouraged to be screened to ensure that they know their hepatitis B status in line with their Health Service Policy and if found to be non-immune should get vaccinated according to their Health Service's policies. Serological evidence of immunity (i.e. anti-HBs >10 mIU/mL) should be obtained 1 month after the 3<sup>rd</sup> dose of hepatitis B vaccine. Vaccinees who fail to develop immunity from the routine 3 dose hepatitis B vaccination course should be offered a single or double dose vaccination or another 3 dose vaccination course with repeat measurement of anti-HBs one month after each dose. Vaccinees who fail to respond to either of these booster schedules should be managed as "non-responders" and receive hepatitis B immunoglobulin following HBV exposure. See attached table: "Post-exposure prophylaxis for hepatitis B virus".

## 7. OTHER HBV HIGH RISK GROUPS

Hepatitis B immunisation is recommended for:

- People who engage in high-risk behaviours, including injecting drug use, sex work, and men who have sex with men (MSM),\*
- People who engage in body piercing,
- People with chronic liver disease or HIV,\*
- People whose occupation brings them into contact with potentially infective blood, body fluids, or contaminated needles, syringes, or other objects,
- Residents and staff of facilities for people with intellectual disabilities,
- Inmates and staff of long-term correctional facilities,
- Dialysis patients or patients who regularly receive blood products,
- Long-term travellers to high risk areas.

\* Vaccine is funded for these groups by the Sexual Health and Blood-Borne Virus Program at CDCD, contact 9388 4841.

Patients on haemodialysis and those who are immunosuppressed should be given a larger dose of vaccine (see handbook).

## 8. POST HBV EXPOSURE PROPHYLAXIS

People who may have been exposed to HBV (e.g. sharps injury) should seek medical advice immediately. Prompt treatment with hepatitis B immunoglobulin (400 IU) within 72 hours, combined with hepatitis B immunisation, can prevent subsequent HBV infection. See attached table: 'Post-exposure prophylaxis for hepatitis B virus'. Operational Directive: 0092/07: Policy for Health Care Workers with Blood-Borne Virus Infections, Operational Directive 0091/07: Management of Occupational Exposure to Blood and Body Fluids in the Health Care Setting and Operational Directive 0077/07: Protocol for Non-Occupational Post-Exposure Prophylaxis (NPEP) to Prevent HIV in Western Australia.

## 9. VACCINE ADVERSE EFFECTS

The hepatitis B vaccine is very safe. Serious adverse effects following hepatitis B vaccination, including anaphylaxis, are very rare. Common temporary side effects include soreness at the injection site (5-15%), fever (2-3%), or nausea, dizziness, weakness, aches and pains (<1%). There is no reliable evidence that hepatitis B vaccine causes any chronic illness.

## 10. VACCINE BOOSTERS

Routine hepatitis B vaccine boosters, including the 5 yearly boosters previously recommended for health care workers, are no longer recommended routinely due to the demonstrated long-term immune memory from successful hepatitis B immunisation. However, booster doses are recommended for individuals with impaired immunity, in particular those with either HIV infection or renal failure.

## 11. VACCINE SUPPLIES

Hepatitis B vaccine for publicly funded vaccine programs is available through the routine childhood vaccine sources — CSL (Phone: 9328 7322) in the metropolitan area and regional pharmacies in rural areas.

## 12. CONSENT

Appropriate written and/or verbal information on the benefits and risks of the vaccination, and on the nature of adverse events following the vaccination, must be provided to the parents/guardians of minors prior to the hepatitis B vaccination. Information on the risks and benefits of hepatitis B vaccination is contained in the attached hepatitis B fact sheets.

Parents/guardians must indicate their consent for their child to be vaccinated either verbally or in writing before the vaccinator can proceed with any vaccination.

- **Opportunistic Immunisation**

Vaccination providers are encouraged to review the vaccination status of the child/adult at each encounter and where appropriate give or arrange for any other vaccinations that are scheduled for that particular age group to be given.

## MORE INFORMATION

- NHMRC Australian Immunisation Handbook 9th Edition: <http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook-home>

For more information contact your Local Public Health Unit

Public Health Unit	Telephone/Fax No.	Public Health Unit	Telephone/Fax No.
<b>North Metropolitan</b> (Perth)	Tel: 9380 7700 Fax: 9380 7719	<b>Kimberley</b> (Broome)	Tel: 9194 1630 Fax: 9194 1633
<b>South Metropolitan</b> (Perth)	Tel: 9431 0200 Fax: 9431 0223	<b>Midwest</b> (Geraldton)	Tel: 9956 1985 Fax: 9956 1991
<b>Great Southern</b> (Albany)	Tel: 9842 7500 Fax: 9842 2643	<b>Goldfields</b> (Kalgoorlie)	Tel: 9080 8200 Fax: 9080 8201
<b>Southwest</b> (Bunbury)	Tel: 9781 2350 Fax: 9781 2382	<b>Wheatbelt</b> (Northam)	Tel: 9622 4320 Fax: 9622 4342
<b>Midwest</b> (Carnarvon)	Tel: 9941 0570 Fax: 9941 0563	<b>Pilbara</b> (Port Hedland)	Tel: 9172 8333 Fax: 9172 8370

Central Immunisation Clinic  
16 Rheola Street, West Perth  
Telephone: (08) 9321 1312

Internet <http://www.cdc.gov/>  
<http://www.phls.co.uk/>  
<http://www.who.int/>  
<http://www.health.gov/nhmrc/><http://www.public.health.wa.gov.au/1/51/2/immunisation.pm>



Government of **Western Australia**  
 Department of **Health**  
**Communicable Disease Control Directorate**

# Hepatitis B

## January 2009

### What is hepatitis B?

Hepatitis B is an infectious disease of the liver caused by the hepatitis B virus (HBV). About 50% of adults and 10% of children develop symptoms after HBV infection, which can be acute (short-term) or chronic (long-term).

### What is acute hepatitis B?

About 20 to 50 acute cases of HBV infection are reported in WA each year. Most of these cases are between 15 and 40 years of age. After an incubation period of 2 to 6 months, HBV infection can cause an illness with symptoms including tiredness, loss of appetite, nausea, weight loss, abdominal discomfort, and jaundice (yellowing of the skin and whites of the eyes and dark-coloured urine). Less common symptoms include fever, arthritis, and rash. About 1 in 100 hospitalised patients die from acute HBV infection. Although most acute cases are associated with unsafe sex or drug injecting practices, the source of infection for many other cases is unknown.

### What is chronic hepatitis B?

About 95% of adults infected with the HBV make a complete recovery. However, up to 90% of babies and 5% of older children and adults are unable to get rid of the HBV and remain infected for many years, even though they usually do not have any symptoms? People with chronic HBV infection are called hepatitis B 'carriers' and can infect other people with the HBV. In Australia, about one person in every 1,000 is a hepatitis B carrier and about 1 in 5 carriers will die prematurely of either cirrhosis (liver failure) or liver cancer (about 20 years after infection). Adults from Central or South America, Southern or Eastern Europe, Africa, India, the Middle East, China, South East Asia, the Pacific Islands, or indigenous Australians have a higher proportion of chronic HBV infection.

### How is hepatitis B spread?

Blood is the most infectious source of the HBV, but other body fluids including semen, vaginal secretions, saliva and breast milk can also transmit the HBV. Tears, sweat, urine, and faeces do not appear to transmit the HBV. Both acute and chronic hepatitis B patients are infectious. In developing countries, babies born to mothers with chronic hepatitis B are often infected with the HBV during birth.

### What is the treatment for hepatitis B?

There is no effective, specific treatment for acute HBV infection. However, there are some drugs available for the treatment of chronic HBV infection, including alpha-interferon.

### How do I avoid catching hepatitis B?

HBV transmission can be prevented by:

- Vaccination
- Not sharing any drug injecting equipment (e.g. needles, syringes, spoons, tourniquets, water)
- Not having unprotected sex.
- Not sharing toothbrushes, dental floss, razors, or nail files.
- Demanding sterile equipment for tattooing, ear or body-piercing, acupuncture or electrolysis.
- Immediately cleaning and dressing wounds.

### What do I do if I think I've been exposed to hepatitis B?

See your doctor immediately. If you haven't been vaccinated against hepatitis B and you've only been exposed to the HBV recently (within 3 days), your doctor can prevent you catching hepatitis B by giving you hepatitis B immunoglobulin and hepatitis B vaccine. If you were exposed to the HBV a long time ago your doctor can test your blood to see if you were infected.





Government of **Western Australia**  
Department of **Health**  
**Communicable Disease Control Directorate**

# Post-Exposure Prophylaxis for Hepatitis B Virus January 2009

Vaccination and antibody response status of exposed workers*	TREATMENT		
	Source HBsAg <sup>†</sup> positive	Source HBsAg <sup>†</sup> negative	Source Unknown or not available for testing
<b>Unvaccinated</b>	HBIG <sup>§</sup> x 1 and initiate HB vaccine series <sup>¶</sup>	Initiate HB vaccine series	Initiate HB vaccine series
<b>Previously vaccinated</b>			
Known responder**	No treatment	No treatment	No treatment
Known non-responder <sup>††</sup>	HBIG x 1 and initiate revaccination or HBIG X 2 <sup>§§</sup>	No treatment	If known high risk source, treat as if source were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs <sup>¶¶</sup>  1. If adequate,** no treatment is necessary. 2. If inadequate, <sup>††</sup> administer HBIG x 1 and vaccine booster.	No treatment	Test exposed person for anti-HBs <sup>¶¶</sup>  1. If adequate, ** no treatment is necessary. 2. If inadequate, <sup>††</sup> administer vaccine booster and recheck titre in 1-2 months.

\* Persons who have previously been infected with HBV are immune to reinfection and do not require post-exposure prophylaxis.

† Hepatitis B surface antigen.

§ Hepatitis B immune globulin; dose is 400 IU by IM intramuscularly (100 IU for children weighing up to 30kg). The dose should be given within 72 hours of exposure (page 162 of the handbook).

¶ Hepatitis B vaccine. The course should be commenced within 7 days of exposure and followed with two further doses.

\*\* A responder is a person with adequate levels of serum antibody to HBsAg (i.e. anti-HBs  $\geq$  10 mIU/mL).

†† A non-responder is a person with inadequate response to vaccination (i.e. serum anti-HBs < 10 mIU/mL).

§§ The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for non-responders who have not completed a second 3 dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

¶¶ Antibody to HBsAg.

Source: Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post-exposure Prophylaxis. *MMWR* 2001; 50(No. RR-11):22

The Australian Immunisation Handbook, 9<sup>th</sup> Ed, 2008. NHMRC.

<http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook-home>



Government of Western Australia  
 Department of Health  
 Communicable Disease Control Directorate

# Hepatitis B Request Form for Vaccines

**TO: Vaccine Distribution Officer**

**FAX: Metropolitan: 9388 4820**

**PHONE: 9388 4838**

**FAX: Regions: Your local Regional Pharmacy**

**NAME:**

(Requesting Doctor/Nurse) .....

**SUBJECT: HEPATITIS B VACCINE FOR NON-IMMUNE CONTACTS OF HEPATITIS CASE**  
**Hepatitis B for immunisation catch up program**

Please supply Hepatitis B vaccine doses to the attending doctor as indicated below:

**Attending**

**Doctor/Nurse:** .....

**Telephone:** .....

**Delivery Address:** .....

**Postcode:** .....

**Hepatitis B Vaccine for contacts of a case: Adult H-B-VAX II x 3 doses to complete course**

**Number of doses requested:** ..... **Doses**

**Contact's Name:** .....

**Contact's date of birth:** ..... / ..... / .....

**Delivery required by: Date:** ..... / ..... / ..... **Time:** ..... am / pm

**Hepatitis B Vaccine: for immunisation catch up program Paediatric**  
**H-B-VAX II x 3 doses to complete the course / School-based course – 2 adult doses**  
**of H-B-VAX II**

**Name:** .....

**Date of birth:** ..... / ..... / 200.....

**Delivery required by: Date:** ..... / ..... / ..... **Time:** ..... am / pm

**Signature of attending Doctor/Nurse:** .....

**Date:** ..... / ..... / ..... **Time:** ..... am / pm