Hepatitis B vaccines for Australians

This fact sheet provides information on hepatitis B disease and the available vaccines to assist immunisation providers in the delivery of hepatitis B vaccinations.

**Disease and epidemiology**

- Hepatitis B is a viral infection that primarily affects the liver.
- Hepatitis B virus (HBV) spreads from person to person when broken or penetrated skin, or mucosal membranes are exposed to infected blood or other body fluids (mainly vaginal fluid and semen). It can also spread from an infected mother to her infant at birth.
- Most infected young children are asymptomatic, but up to about 90% will become chronically infected, especially if they are infected perinatally.
- Chronic hepatitis B infection could lead to development of liver cirrhosis and/or hepatocellular carcinoma that account for considerable morbidity and mortality.
- In Australia, groups at increased risk of hepatitis B infection include people who inject drugs, Aboriginal and Torres Strait Islander people, migrants from hepatitis B–endemic regions, men who have sex with men and inmates of correctional facilities.

**Who should be vaccinated?**

- All infants are recommended, and funded under National Immunisation Program, to receive 4 doses of hepatitis B vaccines. These include a birth dose of monovalent hepatitis B vaccine and 3 doses of a hepatitis B–containing hexavalent combination vaccine at 2, 4 and 6 months of age.
- Children and young adolescents who have not received hepatitis B vaccines previously.
- People with increased risk of: (1) exposure to HBV and (2) severe hepatitis B disease.

**Vaccines**

- Hepatitis B vaccines are available either as monovalent antigen formulations or in combination with other vaccine antigens. Hepatitis B vaccine formulations available in Australia are:
  - monovalent hepatitis B vaccines: Engerix-B® and H-B-Vax II® (paediatric and adult formulations)
  - bivalent hepatitis A and hepatitis B vaccines: Twinrix Junior® (360/10) and Twinrix® (720/20)
  - hexavalent combination hepatitis B–containing vaccines: Vaxelis® and Infranrix hexa®

**The disease**

Hepatitis B is caused by hepatitis B virus (HBV). It primarily affects the liver. HBV infects liver cells (hepatocytes) and causes inflammation and immune-mediated damage, leading to liver dysfunction.\(^1,2\) HBV infection can be either acute or chronic, with associated clinical manifestation ranging in severity from asymptomatic to symptomatic and progressive, and even life-threatening, disease. About 80–90% of hepatitis B infections in infancy result in lifelong (chronic) infection that would lead to cirrhosis and liver cancer (liver cirrhosis and/or hepatocellular carcinoma [HCC]).\(^3,4\)

**Cause and transmission**

HBV is an enveloped deoxyribonucleic acid (DNA) virus, with humans as its only known natural host. People with chronic infection act as the major reservoir of infection. When exposed the virus enters the liver of a susceptible person via the blood stream to replicate in hepatocytes. HBV is highly infectious and can survive on environmental surfaces, remaining infectious for up to 7 days.\(^5\)
Transmission of HBV occurs via exposure of broken or penetrated skin, or mucosal membranes to infected blood or other body fluids (mainly vaginal fluid and semen). HBV can spread from an infected mother to her infant at birth (perinatal and vertical transmission) or from person to person (horizontal transmission) through parenteral or mucosal routes. Examples of where parenteral transmission would occur are sharing of needles and other injecting drug equipment, inadequately sterilised skin penetrating instruments, needle stick injury and household transmission, such as from child to child through contact with open sores or wounds. Mucosal transmission occurs during sexual contact (vaginal, oral and anal sex) and in situations such as splash of blood into eyes or mouth. Certain occupational, behavioural and living conditions increase the likelihood of exposure to HBV-contaminated body fluids. Screening of donated blood for hepatitis B surface antigen (HBsAg) has eliminated the risk of transmission of HBV through blood transfusion in Australia.6

**Diagnosis**

HBV comprises several viral proteins that are used as serological markers (as antigens or antibodies) to identify different phases of infection. Testing for viral proteins and antibodies to specific HBV antigens in the blood is routinely used as the first-line diagnostic method for HBV infection. Nucleic acid tests are also used in hepatitis B diagnosis, and those with high sensitivity can detect HBV DNA in the serum 10–20 days before HBsAg becomes detectable.7

Serological assays are interpreted to determine if an individual is susceptible to HBV, has current active infection, is chronically infected or has immunity acquired either through vaccination or past infection (refer to Table 1).

**Table 1: Interpretation of test results for hepatitis B virus infection**

<table>
<thead>
<tr>
<th>Serological marker</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B surface antigen (HBsAg)</td>
<td>Total antibodies to hepatitis B core antigen (Anti-HBc Ab)</td>
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<tr>
<td></td>
<td>Immunoglobulin M antibodies to hepatitis B core antigen (Anti-HBs Ab)</td>
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<tr>
<td></td>
<td>Antibodies to hepatitis B surface antigen (Anti-HBs Ab)</td>
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<td>+</td>
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<td>+</td>
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</table>

Abbreviations: - = negative, + = positive
Adapted from Plotkin’s vaccines’7

**Clinical features**

**Acute hepatitis B**

The incubation period for acute hepatitis B varies between 45 and 180 days, with an average of about 90 days.1 The period of communicability starts from several weeks before the onset of acute illness and usually lasts 4–5 months. Individuals with chronic HBV infection usually remain infectious for life.1

In young children acute hepatitis B infection is mostly asymptomatic, with only about 10% showing symptoms. Among adults, approximately 30–50% with acute HBV infection would be symptomatic.8 Most
healthy adults are able to eliminate the virus, with only less than a tenth progressing to chronic hepatitis B infection.\textsuperscript{4} Clinical symptoms, when present, are mostly those seen in viral hepatitis in general, not specific to HBV infection, and include fever, malaise, fatigue, anorexia, nausea, vomiting, abdominal pain (especially in the right upper quadrant), myalgia, dark-coloured urine, light-coloured stools, arthritis, rash and jaundice.

During recovery, fatigue and malaise can last for many weeks.\textsuperscript{1,2}

About 1% of acute hepatitis B infections in adults progress to fulminant hepatitis.\textsuperscript{1,9}

**Chronic hepatitis B**

Chronic HBV infection is identified by the persistence of HBsAg in blood for at least 6 months. Some chronic HBV infections may also remain asymptomatic. The likelihood of developing chronic HBV is very high (up to 90%) if HBV infection is acquired in early childhood and infancy, with about 15–25% of these children then developing cirrhosis or HCC that leads to mortality.\textsuperscript{4,10}

Clearance of HBsAg among the chronically infected people is unusual, occurring only in <1% per year.\textsuperscript{2} About 20–30% of adults with chronic HBV will develop cirrhosis or HCC.\textsuperscript{11} Prognostic factors in chronic HBV infection include age of HBV acquisition, HBV viral load, histological factors and associated aggravating factors like alcohol consumption and co-infections with other hepatotropic viruses.\textsuperscript{1,2,10}

**Epidemiology**

Chronic HBV infection is a major public health problem, with the endemicity of active infection (defined as the prevalence of HBsAg in the general population) varying across regions in the world.\textsuperscript{12}

Areas with HBsAg prevalence of 8% or higher are classified as highly endemic. These include Sub-Saharan Africa, East Asia (except Japan), Pacific Island groups and the Amazon basin.\textsuperscript{13-15} In these regions, infections are mainly acquired perinatally or in early childhood.

Areas with HBsAg prevalence of less than 2% are classified as low endemic. These include Australia as well as countries in Central Latin America, North America and Western Europe.\textsuperscript{13}

**Burden of chronic hepatitis B in Australia**

The modelled estimate of the number of people living with chronic hepatitis B infection in Australia in 2017 was 234,000, which equates to a prevalence of 0.9%.\textsuperscript{16} There were 479 deaths that were attributable to chronic HBV infection in that year, with the majority due to HCC.\textsuperscript{16} In the same year, about 40% of people with chronic hepatitis B in Australia were born in regions of moderate or high endemicity.\textsuperscript{16} Aboriginal and Torres Strait Islander people who make up about 3%\textsuperscript{17} of the Australian population accounted for 11% of those with chronic HBV infection.\textsuperscript{16}

Laboratory-confirmed hepatitis B is a nationally notifiable disease. In 2017, the number of notifications to the National Notifiable Diseases Surveillance System (NNDSS) categorised ‘HBV newly acquired’ (i.e. cases where there is laboratory definitive evidence that infection was acquired within the previous 24 months\textsuperscript{16}) was 141 (rate 0.6 per 100,000 population).\textsuperscript{16} This was a 50% reduction from the rate of 1.2 per 100,000 in 2008.\textsuperscript{16}

**Who should be vaccinated**

Hepatitis B vaccination is recommended for groups listed below.

- All infants – hepatitis B vaccines are offered under the National Immunisation Program (NIP)
- Children and adolescents who have not previously received hepatitis B vaccines.
  At present, NIP funds catch-up vaccinations for all people up to 19 years of age who have not received all the vaccines in the NIP schedule. For refugees and humanitarian entrants, catch-up vaccinations are available even if they are older than 20 years.
- People with increased risk of exposure to HBV or severe hepatitis B disease
  Hepatitis B vaccine is recommended for people with an increased risk of exposure to HBV or severe hepatitis B disease (refer to Box 1 for these population groups). Individual states and territories offer funded hepatitis B vaccination for some of these at-risk groups. Refer to state and territory health department websites for eligible groups.
Box 1. Population groups with increased risk of exposure to HBV or severe hepatitis B disease for whom vaccination is recommended

Aboriginal and Torres Strait Islander people

People who are immunocompromised
- people with HIV
- haemodialysis patients
- people receiving a solid organ transplant
- people who have received a haematopoietic stem cell transplant

People with other medical risk factors
- people with chronic liver disease
- people with hepatitis C
- people who receive certain blood products
- people with developmental disabilities who attend day care facilities

People at occupational risk
- healthcare workers
- police, members of the armed forces, emergency services staff and staff of correctional facilities
- staff of facilities caring for people with developmental disabilities
- funeral workers and embalmers
- tattooists and body piercers

People with circumstances that increase their risk of acquiring hepatitis B
- household or other close contacts of people with hepatitis B
- sexual contacts of people with hepatitis B
- sexually active men who have sex with men
- migrants from hepatitis B–endemic countries
- people who inject drugs
- inmates of correctional facilities
- sex industry workers

Travellers to hepatitis B–endemic areas who may be at increased risk

Vaccines

Hepatitis B–containing vaccines registered in Australia are subunit vaccines that contain HBsAg, produced by recombinant DNA technology from yeast cells. These vaccines are safe and highly effective. Hepatitis B vaccines are available either as monovalent antigen formulations or in combination with other vaccine antigens. All these vaccines are administered by intramuscular injection.

Monovalent hepatitis B vaccines

Monovalent hepatitis B vaccines come in paediatric adult and dialysis formulations.

Brand names: Engerix-B, H-B-Vax II

Bivalent combination vaccines containing hepatitis A and B

Brand names: Twinrix Junior, Twinrix


Brand names: Infanrix hexa, Vaxelis
The formulations of the different brands of hepatitis B vaccines are different, and the quantity of HBsAg in their corresponding age-appropriate formulations also differs. For all brands, age-appropriate formulation should be used.

Hepatitis B immunoglobulin (HBIG), obtained from the plasma of immunised and screened human donors, is used to provide passive immunity for immediate, but temporary, protection in situations such as accidental inoculation or contamination with hepatitis B–infected blood while awaiting vaccine response (refer to Use of hepatitis B immunoglobulin).

Interchangeability of hepatitis B vaccines

Switching of vaccine brands is generally not recommended. However, in situations where the brand of vaccine used for previous doses is not known, any age-appropriate formulation may be used, as there is no reason to suggest that using a different brand of the currently available formulations in Australia (Engerix-B and H-B-Vax II) will compromise immunogenicity or safety.19-21

Immune response to vaccination

The standard 3-dose schedule induces protective levels of neutralising antibody against HBV in more than 90–95% of vaccine recipients aged <40 years.1,10,23 An anti-HBs concentration of ≥10 mIU/mL, measured about 1–3 months after completion of a primary vaccine course, is a reliable marker of clinical protection.1 Known factors for poorer vaccine response include ageing (>40 years), smoking, obesity, HIV infection, and some chronic or immunocompromising diseases.1,23 The frequency of seroconversion following vaccination increases progressively from about 35% after the first dose to more than 90% after the third dose.24,25

Vaccine safety and adverse events

Hepatitis B vaccines are safe.1,23,26,27 The birth dose of hepatitis B vaccine is well tolerated by newborn infants with no evidence of interference with either the establishment or maintenance of breastfeeding or any other associated serious adverse events.28-30

Overall adverse events following hepatitis B vaccination are transient and minor. Among adults, reported adverse events include injection site soreness (in 5%), fever (in 2–3% and usually low grade), nausea, dizziness, myalgia and arthralgia.3,8

The estimated incidence of anaphylaxis among children administered hepatitis B vaccine is about 1 in 1.1 million doses.31 Anaphylaxis is reported very rarely in adults, usually in yeast-sensitive individuals.32 Other rare adverse events such as Guillain-Barre syndrome and arthritis have been reported following hepatitis B vaccination but with no evidence of a causal relationship. Multiple studies and review panels have concluded that there is no link between multiple sclerosis and hepatitis B vaccination.23,33-35

Recommended vaccine schedule

There are specific recommendations relating to hepatitis B vaccine formulations and schedules for different age groups and for individuals in certain at-risk groups. When vaccination against both hepatitis B and hepatitis A is indicated for an individual, the combination hepatitis A and hepatitis B vaccines may be used. Refer to Tables 2–4 for recommended schedules for both monovalent and combination hepatitis B vaccines.
### Table 2: Recommended schedule for all infants using monovalent and hexavalent vaccines

<table>
<thead>
<tr>
<th>Recommended schedule – age and/or minimum interval</th>
<th>Vaccine</th>
<th>Dose (HBsAg protein)</th>
<th>Volume per dose (mL)</th>
<th>Number of doses</th>
<th>Alternative schedule - minimum interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>At birth (if not given at birth, may be given up to 7 days of age)</td>
<td>Engerix-B (paediatric formulation) OR H-B-Vax II (paediatric formulation)</td>
<td>10µg OR 5 µg</td>
<td>0.5</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>1st dose*: 2 months of age 2nd dose: 4 months of age (2 months after 1st dose) 3rd dose†: 6 months of age (2 months after 2nd dose)</td>
<td>Infanrix hexa OR Hexaxim</td>
<td>10 µg OR 0.5</td>
<td>3</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

* Can be given at 6 weeks of age; next scheduled doses should still be at 4 and 6 months of age.
† Should preferably be administered at ≥24 weeks of age; however, given at <24 weeks but ≥16 weeks of age, it is not necessary to repeat the dose, provided the minimum intervals between doses have been met.

N/A: Not applicable
<table>
<thead>
<tr>
<th>Recommended schedule – age and/or minimum interval*</th>
<th>Vaccine</th>
<th>Dose (HBsAg protein)</th>
<th>Volume per dose (mL)</th>
<th>Number of doses</th>
<th>Alternative schedule–minimum interval*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Two-dose schedule using monovalent hepatitis B vaccines for people aged 11–15 years</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st dose: day 0 2nd dose: 6 months after 1st dose</td>
<td>Engerix-B (adult formulation)</td>
<td>20 µg</td>
<td>1.0</td>
<td>2</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>H-B-Vax II (adult formulation)</td>
<td>10 µg</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
</tbody>
</table>

| **Three-dose schedule using monovalent hepatitis B vaccines for people aged <20 years** | | | | | |
| 1st dose: day 0 2nd dose: 1 month after 1st dose 3rd dose: 6 months after 1st dose | Engerix-B (paediatric formulation) OR H-B-Vax II (paediatric formulation) | 10 µg OR 5 µg | 0.5 OR 0.7 | 3 | 1st dose: day 0 2nd dose: 1 month after 1st dose 3rd dose: 4 months after 1st dose OR 1st dose: day 0 2nd dose: 2 months after 1st dose 3rd dose: 4 months after 1st dose |

| **Three-dose schedule using monovalent hepatitis B vaccines for people aged ≥20 years** | | | | | |
| 1st dose: day 0 2nd dose: 1 month after 1st dose 3rd dose: 6 months after 1st dose | Engerix-B (adult formulation) OR H-B-Vax II (adult formulation) OR H-B-Vax II (dialysis formulation) | 20 µg OR 10 µg OR 40 µg | 1.0 OR 1.0 OR N/A | 3 | 1st dose: day 0 2nd dose: 1 month after 1st dose 3rd dose: 4 months after 1st dose OR 1st dose: day 0 2nd dose: 2 months after 1st dose 3rd dose: 4 months after 1st dose |

* In these schedules, the ‘day 0’ dose refers to the day when the 1st dose is given (i.e. day 0 of the vaccination course), not the age of the recipient.  
N/A: Not applicable
### Table 4: Recommended schedule for use of combination hepatitis A and hepatitis B vaccines

<table>
<thead>
<tr>
<th>Recommended schedule – age and/or minimum interval*</th>
<th>Vaccine</th>
<th>Dose (HBsAg protein)</th>
<th>Volume per dose (mL)</th>
<th>Number of doses</th>
<th>Alternative schedule-minimum interval*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Combination hepatitis A and hepatitis B vaccines for people aged 1 to &lt;16 years</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1st dose: day 0 2nd dose: between 6 and 12 months after 1st dose</td>
<td>Twinrix (720/20)</td>
<td>20 µg</td>
<td>1.0</td>
<td>2</td>
<td>N/A</td>
</tr>
<tr>
<td>1st dose: day 0 2nd dose: 1 month after 1st dose 3rd dose: 6 months after 1st dose</td>
<td>Twinrix Junior (360/10)</td>
<td>10 µg</td>
<td>0.5</td>
<td>3</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Combination hepatitis A and hepatitis B vaccines for people aged ≥16 years</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>1st dose: day 0 2nd dose: 1 month after 1st dose 3rd dose: 6 months after 1st dose</td>
<td>Twinrix (720/20)</td>
<td>20 µg</td>
<td>1.0</td>
<td>3</td>
<td>N/A</td>
</tr>
</tbody>
</table>

* In these schedules, the ‘day 0’ dose refers to the day when the 1st dose is given (i.e. day 0 of the vaccination course), not the age of the recipient. 
N/A: Not applicable

### Table 5: Recommended 4-dose accelerated schedules

<table>
<thead>
<tr>
<th>Recommended schedule – age and/or minimum interval*</th>
<th>Vaccine</th>
<th>Dose (HBsAg protein)</th>
<th>Volume per dose (mL)</th>
<th>Number of doses</th>
<th>Alternative schedule-minimum interval*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For people aged &lt;20 years</strong></td>
<td></td>
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<tr>
<td>1st dose: day 0 2nd dose: 1 month after 1st dose 3rd dose: 2 months after 1st dose 4th dose: 12 months after 1st dose</td>
<td>Engerix-B (paediatric formula)</td>
<td>10 µg</td>
<td>0.5</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>For people aged ≥16 years</strong></td>
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<tr>
<td>1st dose: day 0 2nd dose: 7 days after 1st dose 3rd dose: 21 days after 1st dose 4th dose: 12 months after 1st dose</td>
<td>Twinrix (720/20)</td>
<td>20 µg</td>
<td>1.0</td>
<td>4</td>
<td>N/A</td>
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<tr>
<td><strong>For people aged ≥20 years</strong></td>
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</table>
### Recommended schedule – age and/or minimum interval*

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dose (HBsAg protein)</th>
<th>Volume per dose (mL)</th>
<th>Number of doses</th>
<th>Alternative schedule minimum interval*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st dose: day 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2nd dose: 1 month after 1st dose</td>
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<tr>
<td>3rd dose: 2 months after 1st dose</td>
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<tr>
<td>4th dose: 12 months after 1st dose</td>
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<tr>
<td>OR</td>
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<tr>
<td>1st dose: day 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd dose: 7 days after 1st dose</td>
<td>20 µg</td>
<td>1.0</td>
<td>4</td>
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<tr>
<td>3rd dose: 21 days after 1st dose</td>
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<tr>
<td>4th dose: 12 months after 1st dose</td>
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</table>

* In these schedules, the ‘day 0’ dose refers to the day when the 1st dose is given (i.e. day 0 of the vaccination course), not the age of the recipient.

N/A: Not applicable

### Infants

All newborn infants are recommended to receive a single birth dose of hepatitis B vaccine using the monovalent paediatric formulation. It should be given as soon as the baby is medically stable, preferably within 24 hours of birth, but may be administered within the first 7 days after birth. This birth dose aims to prevent transmission of HBV to the infant in the first months of life from the mother or household or other close contacts who may have HBV infection.

Following the birth dose, all infants are recommended to receive 3 doses of a hepatitis B–containing vaccine (the hexavalent combination vaccines that also covers protection against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b, ‘DTPa-hepB-IPV-Hib’) at 2, 4 and 6 months of age. Thus, a total of 4 doses of hepatitis B vaccines are recommended in the first year of life. The *Australian Immunisation Handbook* should be consulted if any doses have been missed or if the infant is preterm (born at <32 weeks of gestation) or of low birth weight (<2,000g).

All infants born to mothers with chronic hepatitis B should be given HBIG as well as a birth dose of hepatitis B vaccine, preferably on the day of birth – refer to *Use of hepatitis B immunoglobulin*.

### Children and adolescents

Adolescents are recommended to receive the standard 3-dose schedule using the monovalent vaccine (paediatric formulation) at 0, 1 and 6 months (i.e. doses 2 and 3 given 1 and 6 months, respectively, after the first dose).

*Alternate 2-dose schedule for adolescents* – For adolescents aged 11–15 years, there is an alternative 2-dose schedule using an adult vaccine formulation, with the second dose given 6 months after the first dose (refer to Table 3). This 2-dose schedule produces similar levels of protective antibodies,36,37 with possible better compliance to complete the recommended vaccination schedule.

*HIV positive and immunocompromised children* – Children with HIV are recommended to receive three doses of hepatitis B vaccine using an adult vaccine formulation (i.e. double the standard recommended dose for children). In a limited number of studies,38,39 children who were immunocompromised, including those on haemodialysis, responded better when given higher doses in a 3-dose schedule. These children may require booster doses following regular monitoring of anti-HBs levels. Refer to *Australian Immunisation Handbook*. 

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Hepatitis B vaccines for Australians | NCIRS Fact sheet: June 2023

9
Adults with increased risk of exposure to HBV or severe hepatitis B disease

Adults who are in at-risk groups are recommended to receive the standard 3-dose schedule with an adult vaccine formulation. Adults with HIV and who are on haemodialysis, currently or anticipated, are recommended larger-than-usual doses of hepatitis B vaccine. It is recommended that these adults undergo regular monitoring of their HBsAg levels and receive booster doses of the vaccine, if required (refer to ‘Booster doses’).

Refer to the Australian Immunisation Handbook for further information on specific recommendations for people in risk groups (including solid organ and haematopoietic stem cell transplant recipients).

Serological testing

Routine antenatal screening of all pregnant women for HBsAg is recommended to allow for appropriate measures to prevent HBV infection in newborn infants.

In certain circumstances, people in at-risk groups are recommended to have serological testing before and after hepatitis B vaccination.

Refer to the Australian Immunisation Handbook for more information on serological testing.

Accelerated schedules

Accelerated schedules where recipients attain a seroprotective anti-HBs level in the early months after the commencement of the vaccine course are recommended only for people with imminent risk of exposure such as those intending to travel to hepatitis B–endemic countries with very limited time before departure. The antibody levels following the accelerated schedule are substantially lower at 7 months than those following the standard schedule: therefore, a fourth dose at 12 months needs to be given to complete the accelerated schedule. After the fourth dose the antibody levels are shown to be comparable with or higher than those attained after the standard 3-dose schedule.

Booster doses

Booster doses are recommended for people who are immunocompromised due to HIV infection or renal failure. The time for boosting in such people should be decided by regular monitoring of anti-HBs levels at 6- to 12-monthly intervals.30

Non-responders to the primary vaccination course

A non-responder is someone who has received a primary course of hepatitis B vaccine, but has an anti-HBs level of <10 mIU per mL (measured 4–8 weeks after the primary course). Approximately 5–10% of adult vaccine recipients do not respond to the primary course of hepatitis B vaccine.40 Non-responders are recommended further doses of hepatitis B vaccine after excluding chronic HBV infection.

Persistent non-responders should be informed that they are likely not protected against hepatitis B and so need to minimise exposure to HBV. In case these people have percutaneous or permucosal exposure to HBV, they should receive HBIG within 72 hours.

Contraindications and precautions

The only absolute contraindications for hepatitis B vaccines are:8,12

- anaphylaxis after a previous dose of any hepatitis B vaccine
- anaphylaxis after any component of a hepatitis B vaccine
- anaphylaxis to yeast.

Hepatitis B vaccine is not routinely recommended for pregnant or breastfeeding women. However, according to the World Health Organization, pregnancy and breastfeeding are not contraindications for hepatitis B vaccination.23

The product information for H-B-Vax II states that the vial stopper, syringe plunger stopper and tip cap of the syringe contain latex. An alternative product should be considered for people with an allergy or sensitivity to latex.8
Use of hepatitis B immunoglobulin

Infants born to mothers who are chronically infected with hepatitis B - Infants born to mothers who are chronically infected with hepatitis B need to be given a dose of HBIG of 100IU preferably within 24 hours of birth and certainly within 48 hours of birth. This is in addition to the birth dose of hepatitis B vaccine that should be administered preferably within 24 hours of birth. Testing of antibody response 3–12 months after the completion of the full vaccination course is recommended for these infants.6

Sexual exposure - Non-immune susceptible sexual partners of HBsAg-positive persons should be offered post-exposure HBIG and hepatitis B vaccination; both should be initiated within 14 days of the last sexual contact.6

Persons exposed to blood, body fluids or blood-contaminated secretions - Following significant exposure (percutaneous, ocular or mucous membrane) to blood or body fluids that may potentially contain HBV, where feasible, the source individual should be tested for HBsAg as soon as possible. Depending on the source individual's HBsAg status and the exposed person's immune status, vaccination and HBIG may be required (refer to the Australian Immunisation Handbook for more details regarding HBIG).6

Additional resources for primary medical care/vaccination providers

- The Australian Immunisation Handbook: Hepatitis B disease chapter
- Communicable Disease Network Australia: Series of National Guidelines – Hepatitis B
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