First Edition February 1993

(in Protocol for the control of Hepatitis A, B or C & Hepatitis B vaccination policy in the Northern Territory)

Second Edition February 1999

Third Edition June 2000

Fourth Edition October 2013

Contributors to the preparation of this document.

Stakeholder workshop February 2011

This workshop was facilitated by Karin Mulligan and attended by 30 representatives from:

- Royal Darwin Hospital (RDH)
  - Infectious diseases physicians
  - Specialist laboratory, paediatric and gynaecology staff
- Medical officers from the Aboriginal Medical Services Alliance Northern Territory (AMSANT) and Anyinginyi Health Aboriginal Corporation
- Clinical Professor of Medicine (Sydney University) and specialist hepatologist
- Medical officer Remote Health
- Centre for Disease Control staff.

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<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Changes</th>
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<tr>
<td>4.0</td>
<td>October 2013</td>
<td>Updated by CDC</td>
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<tr>
<td>4.1</td>
<td>November 2013</td>
<td>Appendix 2 updated by the Infectious Diseases Consultant (Liver Clinic)</td>
</tr>
<tr>
<td>4.2</td>
<td>August 2014</td>
<td>Footer added re vaccination for Aboriginal and TSI people p11 Reference to Appendix 2 on p22 and p24</td>
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Centre for Disease Control
Department of Health, Northern Territory 2013

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## Abbreviations

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<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>ACIR</td>
<td>Australian Childhood Immunisation Register</td>
</tr>
<tr>
<td>ALT/AST</td>
<td>alanine aminotransferase / aspartate aminotransferase</td>
</tr>
<tr>
<td>Anti-HBc</td>
<td>hepatitis B core antibody</td>
</tr>
<tr>
<td>Anti-HBe</td>
<td>hepatitis B e antibody</td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>hepatitis B surface antibody</td>
</tr>
<tr>
<td>ASH</td>
<td>Alice Springs Hospital</td>
</tr>
<tr>
<td>BMI</td>
<td>body mass index</td>
</tr>
<tr>
<td>CARPA</td>
<td>Central Australian Rural Practitioners Association (Handbook)</td>
</tr>
<tr>
<td>CCIS</td>
<td>Community Care Information System (patient record management for some Department of Health programs including immunisation)</td>
</tr>
<tr>
<td>CDC</td>
<td>Centre for Disease Control (Northern Territory)</td>
</tr>
<tr>
<td>DNA</td>
<td>deoxyribonucleic acid</td>
</tr>
<tr>
<td>DNA VL</td>
<td>deoxyribonucleic acid viral load</td>
</tr>
<tr>
<td>DoH</td>
<td>Department of Health (Northern Territory)</td>
</tr>
<tr>
<td>DTPa-HepB-IPV-HIB</td>
<td>Diphtheria, tetanus, pertussis, hepatitis B, polio, <em>Haemophilus influenzae</em> B combination vaccine. Trade name Infanrix®Hexa</td>
</tr>
<tr>
<td>eGFR</td>
<td>estimated glomerular filtration rate</td>
</tr>
<tr>
<td>g</td>
<td>gram</td>
</tr>
<tr>
<td>HBeAg</td>
<td>hepatitis B e antigen</td>
</tr>
<tr>
<td>HBIG</td>
<td>hepatitis B immunoglobulin</td>
</tr>
<tr>
<td>HBsAg</td>
<td>hepatitis B surface antigen</td>
</tr>
<tr>
<td>H-B-VAXII</td>
<td>hepatitis B vaccine (adult)</td>
</tr>
<tr>
<td>HBV DNA</td>
<td>hepatitis B virus DNA</td>
</tr>
<tr>
<td>HCV</td>
<td>hepatitis C virus</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>IgG</td>
<td>immunoglobulin G</td>
</tr>
<tr>
<td>IgM</td>
<td>immunoglobulin M</td>
</tr>
<tr>
<td>INR</td>
<td>international normalized ratio</td>
</tr>
<tr>
<td>IU</td>
<td>international units</td>
</tr>
<tr>
<td>L</td>
<td>litre</td>
</tr>
<tr>
<td>mL</td>
<td>millilitre</td>
</tr>
<tr>
<td>NIP</td>
<td>National Immunisation Program</td>
</tr>
<tr>
<td>NT</td>
<td>Northern Territory</td>
</tr>
<tr>
<td>Paed</td>
<td>paediatric</td>
</tr>
<tr>
<td>PCIS</td>
<td>Primary Care Information System (patient record management system used in some remote health centres)</td>
</tr>
<tr>
<td>RDH</td>
<td>Royal Darwin Hospital</td>
</tr>
<tr>
<td>μg</td>
<td>micrograms</td>
</tr>
</tbody>
</table>
1 Introduction

The Department of Health (DoH), Centre for Disease Control first issued a Protocol for the Control of Hepatitis A, B and C and Hepatitis B Vaccination Policy in the Northern Territory in 1992. These guidelines for health professionals included information about notification requirements, contact tracing, surveillance forms and fact sheets as well as background information about hepatitis B and the newly introduced vaccination policy. Subsequent editions focussed on hepatitis B vaccination with a short public health management section.

This 2013 edition has included additional Northern Territory (NT) hepatitis B epidemiology, testing recommendations, management of those with hepatitis B infection and specialist referral guidelines.

Hepatitis B is caused by the hepatitis B virus, a DNA virus that primarily replicates in the liver. Infection occurs in susceptible people through percutaneous and mucosal exposure to infected blood and blood products, saliva and body fluids (cerebrospinal, peritoneal, pericardial, synovial and amniotic fluid, semen and vaginal secretions or any other body fluid containing blood).\(^1\)

Transmission occurs most commonly via sexual or close household contact, from mother to infant perinatally, through injecting drug use or through nosocomial exposure.\(^1\)

The incubation period is 45-180 days, usually 60-90 days.\(^1\)

Cases are infectious some weeks before symptoms develop and remain so while HbsAg positive.

Children are more likely to have asymptomatic infection with only 10% presenting with clinical disease. Conversely, 30-50% of adults will be symptomatic.\(^1,2\)

Presenting symptoms include anorexia, right upper quadrant pain, nausea, and jaundice. Symptoms usually disappear 1-3 months after onset.\(^2\)

The probability of developing chronic infection varies according to age at acquisition. 90% of neonates who acquire the infection from their mothers will develop chronic infection while only 5% of those who acquire the infection in adulthood will do so.\(^2\)

People with chronic infection are at high risk of chronic liver disease, cirrhosis and hepatocellular carcinoma.
2 Epidemiology

2.1 The epidemiology of hepatitis B in the Northern Territory

Hepatitis B has been a notifiable disease in the NT since 1992 but until late 2005 only acute cases were recorded. Since 2006 all cases of hepatitis B infection have been notifiable and have been recorded on the NT Notifiable Diseases System.

There are only a few recent studies on the epidemiology of hepatitis B in the NT. In July 2012, a report in the Northern Territory Disease Control Bulletin summarised the notification data while more recently a data linkage study which examined the effect of birth cohort on the infection rate in antenatal women was published.

Notification data are comprehensive but biased by the degree of testing which takes place and this can vary widely according to both the geography (some communities more than others) and birth cohort (adults more than children). On the other hand, antenatal women are universally screened so estimates are likely to be more accurate even though they only include one part of the population.

Both studies noted that the patterns of hepatitis B chronic infection in the NT are influenced mainly by Indigenous status, birth cohort (born before or after the vaccine era) and, to a lesser extent, geography (Top End/Centre or rural/urban). Analysis did not include country of birth which is not collected in the NT Notifiable Diseases System.

The antenatal study found that, in the Indigenous population, prevalence fell from 3.5% in those Indigenous women born before the vaccine era (before 1982) to 0.8% in those born in the vaccine era (1989 and later). Those born between 1982 and 1988, who were eligible for the catch-up program had a prevalence of 2.2%. There was a higher prevalence in women who lived in remote areas in whom the prevalence fell from 5% in the pre-vaccine cohort to 1% in the vaccine cohort.

Analysis of notification data revealed an overall Indigenous rate of 2.66% compared with the non-Indigenous rate of 0.41%; a rate ratio of 6.4 (95%CI; 6.14-6.74). Those born before the vaccine era (before 1990) had a much higher prevalence of infection than those born in 1990 or after. This is illustrated in Table 1.

Table 1. Prevalence of hepatitis B infection by Indigenous status and vaccine era

<table>
<thead>
<tr>
<th></th>
<th>Indigenous (%)</th>
<th>Non-Indigenous (%)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Born before 1990</td>
<td>4.72</td>
<td>0.47</td>
<td>1.50</td>
</tr>
<tr>
<td>Born in 1990 or after</td>
<td>0.19</td>
<td>0.11</td>
<td>0.14</td>
</tr>
<tr>
<td>% reduction in those born in 1990 or after</td>
<td>96.0%</td>
<td>76.2%</td>
<td>90.3%</td>
</tr>
</tbody>
</table>

In the notification data men had higher rates of hepatitis B infection than women (relative risk 1.44) and this difference did not vary much with Indigenous status.

The different rates across the 7 NT regions are listed in Table 2.
Table 2. Prevalence of hepatitis B infection by region and Indigenous status

<table>
<thead>
<tr>
<th>Region</th>
<th>Number</th>
<th>Indigenous (%)</th>
<th>Non-Indigenous (%)</th>
<th>All (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alice Springs Rural</td>
<td>356</td>
<td>3.07</td>
<td>0.29</td>
<td>2.52</td>
</tr>
<tr>
<td>Alice Springs Urban</td>
<td>345</td>
<td>4.45</td>
<td>0.34</td>
<td>1.20</td>
</tr>
<tr>
<td>Barkly</td>
<td>52</td>
<td>1.05</td>
<td>0.30</td>
<td>0.78</td>
</tr>
<tr>
<td>Darwin Rural</td>
<td>265</td>
<td>2.03</td>
<td>0.40</td>
<td>1.57</td>
</tr>
<tr>
<td>Darwin Urban</td>
<td>694</td>
<td>1.32</td>
<td>0.45</td>
<td>0.55</td>
</tr>
<tr>
<td>East Arnhem</td>
<td>548</td>
<td>4.89</td>
<td>0.42</td>
<td>3.25</td>
</tr>
<tr>
<td>Katherine</td>
<td>244</td>
<td>2.12</td>
<td>0.19</td>
<td>1.22</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2504</td>
<td><strong>2.66</strong></td>
<td><strong>0.41</strong></td>
<td><strong>1.09</strong></td>
</tr>
</tbody>
</table>

The prevalence in Central Australia was 1.57 times that of the Top End (95% CI: 1.44-1.70; p<10⁻⁵) while rural prevalence was almost 3 times that of urban (RR=2.94:95% CI;2.71-3.18; p<10⁻⁵). The highest prevalence was in the East Arnhem region.

Figure 1 illustrates the prevalence of hepatitis B infection by birth cohort, demonstrating the drop in prevalence in those born in the vaccine era but also demonstrating that prevalence increases with age. This might suggest that transmission continues throughout adulthood, or that prevalence was declining prior to the vaccine era.

Analysis of community specific data using census population figures suggests that in some communities age-specific rates in adult males could be as high as 25%.

**Figure 1. Prevalence of hepatitis B infection by birth cohort and Indigenous status**

![Figure 1](image-url)
Previous studies using community-based surveys of small numbers have found higher rates of chronic infection – up to 12% in those over 15 years of age.\textsuperscript{5,6} The analysis of notification data is likely to be biased by the degree of testing and in particular may underestimate the number of cases born in the vaccine era (because children are rarely tested).
3 Immunisation

3.1 Background

Hepatitis B vaccines have been included in the NT Childhood Immunisation Schedule since 1988.

While initially hepatitis B vaccination was only offered programmatically to high risk newborn infants this was expanded in 1990 to include all newborns. The vaccine is now routinely administered as part of the National Immunisation Program (NIP) to all babies at birth, 2, 4 and 6 months of age (see Appendix 1 for dates that the schedule changes were introduced).

Hepatitis B vaccine is available as either a monovalent or combination vaccine. It should always be stored between 2 – 8°C and protected from light. Freezing will render the vaccine ineffective. Further information can be found in the National vaccine storage guidelines: Strive for 5.\(^7\)

3.2 General vaccine information

3.2.1 Minimal intervals

Minimum time frames exist for the spacing between doses of the monovalent hepatitis B vaccines and Infanrix\(^\circ\) Hexa (DTPa-HepB-IPV-Hib).

Between:
- Dose 1 and 2 = 4 weeks (1 month interval)
- Dose 2 and 3 = 8 weeks (2 month interval)
- Dose 1 and 3 = 16 weeks (4 month interval).

For infants, the final dose of the primary course should not be administered before 24 weeks (6 months) of age.

3.2.2 Delayed schedule completion

If the primary course of 3 doses of vaccine is not completed according to the recommended timeframes, do not restart the series even if more than 1 year has elapsed since the previous dose. Vaccine doses administered at longer intervals provide equally satisfactory protection, however optimal protection is not conferred until after dose 3 is completed.

3.2.3 Paediatric or adult dose?

Children and those <20 years of age should receive paediatric (0.5mL) hepatitis B vaccine (Table 3).

Adults ≥20 years of age should receive adult (1mL) hepatitis B vaccine.
### Table 3. Hepatitis B and hepatitis A/hepatitis B combination vaccination schedules

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age</th>
<th>Dose (HBsAg protein)</th>
<th>Volume</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monovalent hepatitis B vaccines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Engerix-B (paed)</td>
<td>&lt;20 years</td>
<td>10 µg 0.5mL</td>
<td></td>
<td>0,1,6 mo (3 dose schedule)†</td>
</tr>
<tr>
<td>Engerix-B (adult)</td>
<td>≥ 20 years</td>
<td>20 µg 1.0mL</td>
<td></td>
<td>0,1,6 mo (3 dose schedule)</td>
</tr>
<tr>
<td>H-B-VAXII (paed)</td>
<td>&lt;20 years</td>
<td>5 µg 0.5mL</td>
<td></td>
<td>0,1,6 mo (3 dose schedule)</td>
</tr>
<tr>
<td>H-B-VAXII (adult)</td>
<td>≥ 20 years</td>
<td>10 µg 1.0mL</td>
<td></td>
<td>0,1,6 mo (3 dose schedule)</td>
</tr>
<tr>
<td>H-B-Vax II</td>
<td>≥20 years</td>
<td>40 µg 1.0mL</td>
<td></td>
<td>0,1,6 mo (3 dose schedule)</td>
</tr>
</tbody>
</table>

Dialysis formulation

Combination vaccines used in the NT

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age</th>
<th>Dose (HBsAg protein)</th>
<th>Volume</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infanrix® hexa (DTPa, Hep B, IPV, Hib)</td>
<td>0-10 years</td>
<td>0.5mL</td>
<td></td>
<td>2,4,6 mo (3 dose schedule)†</td>
</tr>
</tbody>
</table>

Combination hepatitis A/B vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age</th>
<th>Dose (HBsAg protein)</th>
<th>Volume</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Twinrix (720/20)§</td>
<td>1-&lt;16 years</td>
<td>20 µg 1.0mL</td>
<td></td>
<td>0,6-12 mo (2 dose schedule)</td>
</tr>
<tr>
<td>Twinrix Junior (360/10)</td>
<td>1-&lt;16 years</td>
<td>10 µg 0.5mL</td>
<td></td>
<td>0,1,6 mo (3 dose schedule)</td>
</tr>
<tr>
<td>Twinrix (720/20)</td>
<td>&gt;16 years</td>
<td>20 µg 1.0mL</td>
<td></td>
<td>0,1,6 mo (3 dose schedule)</td>
</tr>
</tbody>
</table>

* Accelerated hepatitis B vaccination schedule (see Section 3.5).
† Infants receive a birth dose of Hepatitis B vaccine (which should be given within the first seven days of life), followed by 3 doses of combination vaccine (INFANRIX® hexa) at 2, 4 and 6 months of age.
§ This schedule should not be used for those who require prompt protection against hepatitis B.

#### 3.2.4 Interchanging vaccine brands

Using different brands of vaccine for different doses should be avoided if possible. However it is not contraindicated if there is no other vaccine of the same brand available.

#### 3.3 Contraindications

The only contraindication is anaphylactic sensitivity to yeast or any of the vaccine components or previous anaphylactic reaction to the vaccine.
3.4 Vaccine recommendations

Hepatitis B vaccine is recommended and funded under the National Immunisation Program (NIP) for:

- Infants
- Unvaccinated people born on or after 1 August 1990.

Hepatitis B vaccine is recommended for other groups/people but not funded under the NIP. Individuals, employers or the clinical service (health provider) giving the vaccine may choose to fund vaccination* for the following:

- Selected occupational risk groups (Section 3.4.3)
- Other high risk groups (Section 3.4.4).

3.4.1 Infants

Vaccination schedule

The Australian infant schedule consists of a dose of monovalent hepatitis B vaccine given at birth, followed by 3 doses of a hepatitis B containing combination vaccine (Infanrix®-Hexa (DTPa-HepB-IPV-Hib) given at 2, 4 and 6 months of age (Table 3).

Refer to the current NT Childhood Vaccination schedule.


For babies born to HBsAg positive mothers

Babies born to women who are HBsAg positive may be at risk of in-utero transmission. Therefore all pregnant women should be tested for HBsAg, and if positive also tested for HBeAg and HBV viral load. See Appendix 2 for more information.

- If the mother is HBsAg positive, the infant should be given hepatitis B immunoglobulin (HBIG) preferably within 12 hours of birth.
- It is very important that a single dose of hepatitis B vaccine is also administered in the opposing limb at the same time (if this opportunity is missed see overpage).
- The routine hepatitis B vaccine schedule should be completed at 2, 4 and 6 months of age.

Infants born to women who are HBsAg positive should have Anti-HBs and HBsAg levels measured 3-12 months after completing the primary course of vaccination i.e. no earlier than 9 months and ideally at 12 months of age as long as it is 3 months after the last dose. This testing should be entered into a recall system wherever possible. If anti-HBs levels are ≥10 mIU/mL and HBsAg is negative then the children are considered to be immune. For infants who are HBsAg positive refer to specialist (Section 6).

* Note if the clinical service does not fund the vaccine then a prescription should be issued.
HBsAg negative infants with anti-HBs levels < 10 mIU/mL should be investigated for possible HBV infection with HBV viral load testing. If HBV viral load is negative then expert advice regarding revaccination is required for these children.

For babies who miss the birth dose of hepatitis B vaccine
The birth dose of hepatitis B vaccine should preferably be administered within the first 24 hours of life. If the birth dose is either refused or not given within the first 7 days of life this dose should be omitted. Complete the routine doses of hepatitis B containing vaccine at 2, 4 and 6 months of age.

For preterm and low birth weight babies (<32 weeks or <2000g birth weight)
Because preterm and low birth weight babies do not respond as well to hepatitis B vaccination as term babies an additional dose of vaccine is recommended. Babies born at <32 weeks gestation or <2000g birth weight should:

- Have anti-HBs testing at 7 months of age and be given a booster vaccine at 12 months of age if the antibody titre is < 10 mIU/mL

OR

- Be given a booster at 12 months of age without measuring the antibody level.

3.4.2 Unvaccinated people born on or after 1 August 1990
Hepatitis B vaccine was included in the routine childhood vaccination schedule in the NT starting with those children born on or after 1 August 1990. Anyone in the NT born on or after 1 August 1990 who has not already received hepatitis B vaccine as a child or as part of a vaccine program either interstate or overseas is eligible for free vaccine.

3.4.3 Selected occupational risk groups
Groups recommended for vaccination
Hepatitis B vaccine should be offered to the following groups of workers who may be exposed to blood and body fluids through the course of their employment:

Health care workers, including:
- Doctors, nurses, Aboriginal health practitioners and patient care assistants
- Dentists, dental assistants and allied health professionals
- Pathology, laboratory and mortuary staff
- Ambulance personnel

Other occupational groups
- Staff of facilities for people with intellectual disabilities
- Staff of correctional facilities
- Embalmers and funeral workers who have contact with human tissue, blood or body fluids
- Tattooists and body piercers
- Police and emergency services personnel and members of defence forces

* HBV viral load testing is not eligible for Medicare rebate. Please arrange for tests to be funded by the health service.
• Sex industry workers
• Other workers who have regular contact with human tissue blood or body fluids or used needles or syringes.

**Vaccine funding**

Hepatitis B vaccines for occupationally at risk groups are funded by the employer or employee.

Eligible Department of Health (DoH) staff should have vaccine charged to their relevant cost code.

Private workplace employers who wish to vaccinate their staff should be directed to an occupational health service or private general practitioner (GP) for prescription and vaccine administration.

### 3.4.4 Other high risk groups

**Groups recommended for vaccination**

- Aboriginal and Torres Strait Islander people*
- Migrants from hepatitis B high prevalence countries\(^8\)
- Regular recipients of blood products
- Household contacts\(^†\) and sexual partners\(^‡\) of people who have acute or chronic hepatitis B infection including families adopting children from overseas countries if child is HBsAg positive
- Men who have sex with men
- Inmates of correctional facilities
- Residents of facilities for people with intellectual disabilities
- People who inject drugs
- People on opiate pharmacotherapy programs
- Travellers and emigrants to regions where hepatitis B is of high prevalence\(^8\)
- Patients on maintenance haemodialysis, peritoneal dialysis or patients who have undergone renal transplantation (see additional information below)
- Solid organ and haematopoietic stem cell transplant recipients
- HIV positive individuals and other immunocompromised persons
- People with chronic liver disease and/or Hepatitis C who are HBsAg negative.

**Vaccine funding**

_Hepatitis B vaccines for other high risk groups are either funded by the clinical service providing the vaccine or self funded. Vaccine for household and sexual contacts should be provided free of charge. If this is not possible from the service provider the local CDC should be contacted for assistance._

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* Specifically targeting those aged 15-50 years without previous vaccination or anti-HBs or past infection (anti-HBc positive) from patient records and NT Immunisation Register.

† For practical purposes household contacts are defined as those who have spent more than 4 weeks of the last 6 months living in the case’s house (see Section 5.1).

‡ Current sexual contacts and those with sexual contact in the last 6 months.
3.4.5 Patients with special vaccination requirements

While they may be at increased risk for hepatitis B infection, HIV positive adults, haemodialysis patients and other immunocompromised patients respond less well to vaccination and therefore benefit from a larger dose of vaccine.

Haemodialysis patients and patients with impaired renal function (in whom dialysis is anticipated)

A larger dose of vaccine is required for patients (aged ≥20 years) on dialysis and those with stage 4 or 5 renal disease with eGFR ≤30.

This should be administered as either:

- H-B-VAX II dialysis formulation (40μg/1mL) using a 0, 1 and 6 months schedule

OR

- A 4 dose schedule at 0, 1, 2 and 6 months using 2 doses of Engerix-B 20 μg/1mL (1 dose given simultaneously in each arm at each encounter).

HIV-positive and other immune compromised people

Recommended schedule for HIV-positive patients.

- Adults: 4 dose schedule at 0, 1, 2 and 6 months using 2 doses of Engerix-B 20 μg/1mL (1 dose given simultaneously in each arm at each encounter).
- Children: 3 dose schedule of hepatitis B adult formulation.

For risk levels of immunosuppression for other conditions see Appendix 3 and refer to the Australian Immunisation Handbook, p145, Vaccination of immunocompromised persons.8

Post vaccination testing for patients with HIV infection and renal patients

Post vaccination testing at 4-8 weeks is recommended.

- If seroconversion does not occur (conversion to anti-HBs ≥10 mIU/mL) after a prescribed primary course manage as a non-responder to primary vaccination (Section 3.8).

An anti-HBc negative patient who does not seroconvert to anti-HBs positive after 2 full hepatitis B vaccination courses, requires annual serology for HBsAg. Persistent non-responders should be discussed on an individual basis with the CDC immunisation team or a renal physician. They should also be given information about the need for minimising exposure and accessing HBIG within 72 hours of parenteral exposure to HBV.

Anti-HBs levels should be monitored at 6-12 monthly intervals following vaccination. Note: people with prior hepatitis infection should be followed up according to Section 6, Management of hepatitis B infection in primary care.

- All anti-HBc negative patients with anti-HBs ≥10 mIU/mL require 6-12 monthly testing to ensure anti-HBs remains ≥10 mIU/mL.
- If anti-HBs is ≤10 mIU/mL then further booster vaccination is required.

For information on interpretation of test results see Appendix 4.
3.5 Accelerated vaccination schedule

Where rapid protection is required (e.g. travellers) see Table 4 below

Table 4. Accelerated hepatitis B vaccination schedules*8

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age</th>
<th>Dose (HBsAg protein)</th>
<th>Volume</th>
<th>Schedule (mo=months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engerix B (Paed)</td>
<td>&lt;20 years</td>
<td>10µg</td>
<td>0.5mL</td>
<td>0,1,2,12 mo</td>
</tr>
<tr>
<td>Engerix B (Adult)</td>
<td>≥20 years</td>
<td>20µg</td>
<td>1.0mL</td>
<td>0,1,2,12 mo OR 0,7,21 days,12 mo</td>
</tr>
<tr>
<td>Twinrix (720/20)</td>
<td>≥16 years</td>
<td>20µg</td>
<td>1.0mL</td>
<td>0,7,21 days,12 mo</td>
</tr>
</tbody>
</table>

* As higher seroprotective rates are seen after the 0, 1, 2 month schedule it is recommended that the 0, 7, 21 days schedule be used only in adults and only in exceptional circumstances. In both schedules, a booster dose at 12 months is recommended for long term protection.

3.6 Booster doses

Booster doses are not recommended for immunocompetent individuals after the primary course of hepatitis B vaccination. This applies to children, adults and includes health care workers. Booster doses are only recommended for immunosuppressed individuals, including those with HIV infection and renal failure. The timing of booster doses in renal and HIV infection will depend on results of 6-12 monthly anti-HBs levels (Sections 3.4.5 and 5.2, or consult with treating specialist).

3.7 Post vaccination testing

Testing 4-8 weeks after vaccination is only recommended for:

- Those at significant occupational risk e.g. health care workers
- Those at risk of severe or complicated disease e.g. people who are immunocompromised or with pre-existing liver disease
- Those in whom a poor response to vaccination is expected (Section 3.4.5)
- Sexual partners and household contacts of recently notified hepatitis B carriers (Section 5.2).

Individual employers may elect to fund post-vaccination testing for occupational health and safety reasons beyond any public health indication.

Note: Infants born to hepatitis B HBsAg positive mothers should be tested 3-12 months after completion of the primary course of vaccination, i.e. no earlier than 9 months and ideally at 12 months of age as long as it is 3 months after the last dose (Section 3.4.1).

3.8 Non-responders to primary vaccination

A non-responder is a person who has had a primary course of hepatitis B vaccination who has not developed anti-HBs (>10 mIU/mL) when tested between 4 and 8 weeks after the last dose. Where post vaccination testing is recommended (Section 3.7) and
levels of anti-HBs are <10 mIU/mL, the possibility of chronic infection should be excluded. Those who are HBsAg negative should be offered further vaccination. This can be given as a 4th single booster dose.

People not responding after the 4th dose should have a further 2 doses at monthly intervals and be retested 4 weeks after the final dose.

Subsequent options for non-responders include increased dosing or intradermal administration, discuss with the CDC Immunisation Program.

Persistent non-responders to vaccination should be given information about the need for minimising exposure and accessing HBIG within 72 hours of exposure to HBV.

### 3.9 Vaccination recording

The birth dose of vaccine and immunoglobulin should be recorded:

- On the hospital discharge summary
- In the child’s hand held record (Personal Immunisation record).

The NT Department of Health 'Personal Immunisation Record' should be given to the parent following the first injection (Appendix 5). Vaccine information from the vaccine provider should also be forwarded to the NT Immunisation Register in a timely manner to allow data entry onto the Community Care Information System (CCIS) / Australian Childhood Immunisation Register (ACIR). Subsequent hepatitis B vaccines should be recorded according to service provider protocols and all information forwarded to the NT Immunisation Register. Both adult and childhood vaccinations should be recorded.


* Note information about who should be tested post vaccination, Section 3.7.
4 Testing

4.1 Rationale

Testing for hepatitis B is performed at the population level to detect the asymptomatic early stages of disease so that the infection at this early stage can be treated and complications prevented. As primary prevention has failed (e.g. stopping of acquisition of hepatitis B virus), the aim is secondary prevention to avoid complications. Testing is worthwhile where both early detection and effective treatment is available for a disease with high prevalence and a recognised morbidity and mortality.

When recommending hepatitis B testing, it is important to distinguish between testing for the infection (HBsAg) and testing for disease immunity, in particular vaccine-induced immunity (anti-HBs). Post immunisation testing is recommended only for a few high-risk groups and this testing should be done within 4-8 weeks of completing the course (see Section 3.7). After this time a negative test is difficult to interpret (see Appendix 6).

There is no evidence that testing vaccinated populations for an adequate immunisation response is beneficial, therefore this is not recommended. There is no recommendation for testing for immunity (anti-HBs) in any immunised population, apart from a few well-defined high risk groups as outlined in Section 3.7.

Testing asymptomatic patients for hepatitis B infection carries a responsibility for your clinical service to evaluate and manage those patients who are found to have chronic infection (with assistance from the liver clinic).

4.2 The tests

The tests for hepatitis B infection should be as follows:

- HBsAg to indicate current infection
- Anti-HBc to indicate exposure (past or current infection). Anti-HBc indicates current immunity if HBsAg is negative.*

Testing for anti-HBs at the population level is not recommended. Antibody levels can decrease to undetectable levels without signifying loss of immunity so a negative test is difficult to interpret in vaccinated individuals.

4.3 Testing process

People who have not been immunised or shown to be immune should be tested for HBsAg and anti-HBc. Those who are HBsAg positive should be managed according to guidelines (Section 6 – Management of hepatitis B infection in primary care).

* A very small proportion of those with HBcAb positive and HBsAg negative results will have chronic ‘ occult’ HBV infection. This is unlikely to be of any clinical significance because these cases generally have low viral loads, have low infectivity and tend not to progress to chronic liver disease. Those with HBcAb who have unexplained raised LFTs or who become immunosuppressed need further testing for HBV viral load.
Those who are HBsAg negative but anti-HBc positive should be considered immune and a note made in their medical record to that effect. They should not undergo further testing unless clinically indicated, such as if they become immunocompromised or develop unexplained abnormal liver function. These clients should be advised not to donate blood.

Unvaccinated people who are HBsAg negative and anti-HBc negative are non-immune and not infected. Vaccination is recommended for people at risk of exposure, but consideration should be given to the resources available to achieve this at the population level (refer to vaccination funding information Sections 3.4.3 and 3.4.4). Those who remain unvaccinated should be tested again as indicated in Table 5.
4.4 Groups to be tested and vaccinated if found to be non-immune

Table 5. Risk groups recommended for testing

| People who are fully vaccinated or are known to be anti-HBc/anti-HBs positive should not be tested |
|---|---|
| Risk group | Frequency |
| Aboriginal and Torres Strait Islander people between 15 and 50 years | Second yearly with adult health check* |
| People with a sexually transmitted infection and those requesting a sexual health check up | Each presentation if not already immune* |
| People from high prevalence countries§ | Once after arrival from that country* |
| Men who have sex with men | As part of the annual check* |
| People who inject drugs | As part of the annual check* |
| Sex industry workers | As part of the annual check* |
| People with chronic liver disease in particular chronic hepatitis C | On diagnosis |
| Inmates of correctional facilities | On reception* |
| Pregnant women as part of the routine antenatal check | Once every pregnancy*†‡ |
| Haemodialysis patients, HIV-positive individuals and those with impaired immunity or who will become immunosuppressed§ | 6-12 monthly testing is required (see section 4.3) |

* First check for previous vaccination or anti-HBs or past infection (anti-HBc positive) in patient records and NT Immunisation Register.
† For pragmatic reasons this includes those who have been immunised. The test is usually HBsAg only and is included in the antenatal screening batch.
‡ RANZCOG guideline recommends testing every pregnancy irrespective of immunisation status or known anti-HBc status.
§ See Appendix 3, risk levels of immunosuppression, where levels 2 and 3 are considered immunosuppressed.
Vaccination is recommended for IVDU with anti-HBc as this may be a false positive.

Further testing for hepatitis B infection may be warranted for other reasons. The recommendation here relates to testing at the population level.

Depending on resources available for population vaccination program.
5 Contact tracing

The extent of contact tracing will be informed by an assessment of the likely source and timing of infection.

5.1 Definition

The following contacts will need to be considered for follow up and testing:

- Household contacts* – those who have spent more than 4 weeks of the last 6 months living in the case’s house. Priority should be given to those that currently reside in the house
- Sexual contacts – current partners and those with sexual contact in the last 6 months
- The mother of the case and the children of female cases, where vertical transmission is considered possible
- Those sharing injecting equipment with the case
- Those with occupational exposure to body fluids of the case
- Other contacts depending on individual assessment of the likely time of acquisition of the case.

5.2 Management

The following testing and management of contacts should be undertaken with their informed consent and initiated by the clinician managing the patient:

- Those shown to be previously immune (HBsAg negative and anti-HBc positive or evidence of anti-HBs >10IU at any time) do not need to be retested
- Where contacts have documented history of immunisation but the response to previous vaccination is unknown then anti-HBs should be determined as quickly as possible
- Any contacts who are HBsAg positive should be managed according to Section 6
- Contacts who are anti-HBc negative and HBsAg negative and continue to be exposed to the case, should be recommended for vaccination. For household contacts priority should be given to current sexual partners and current regular household members. Non-immune contacts manage according to Section 5.3
- Post vaccination serological testing 4-8 weeks after completion of the course is recommended for sexual and household contacts.

Vaccine for contacts of hepatitis B should be provided free. If this is not possible from the service provider then contact CDC for assistance (see Section 3.4.4).

* For practical purposes household contacts are defined as those who have spent more than 4 weeks of the last 6 months living in the case’s house.
5.3 Post exposure prophylaxis

Non-immune contacts with significant isolated exposure*† within the past 72 hours should be offered immediate post-exposure prophylaxis with hepatitis B immunoglobulin (HBIG) and vaccination commenced (Table 6). HBIG is derived from blood donors and is a scarce resource. Its use needs to be weighed up against the absolute risk of acquisition from the most recent contact.

Where the contact is non-immune and the status of the source patient is unknown consideration should be given to the likely status of the source. Discussion with an infectious diseases physician/registrar or sexual health physician is recommended.

Table 6. Post exposure prophylaxis for non-immune persons exposed to a HBsAg positive person

<table>
<thead>
<tr>
<th>Type of exposure</th>
<th>Hepatitis B immunoglobulin</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perinatal (exposure of babies during and after birth)</td>
<td>100 IU IM</td>
<td>Single dose immediately after birth (preferably within 12 hours of birth and certainly within 48 hours)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immediately after birth preferably within 24 hours, no later than 7 days† then at 2, 4 and either 6 or 12 months of age</td>
</tr>
<tr>
<td>Percutaneous, ocular or mucous membrane</td>
<td>400 IU IM</td>
<td>Single dose within 72 hours of exposure</td>
</tr>
<tr>
<td></td>
<td>100 IU IM</td>
<td>If body weight &lt;30kg</td>
</tr>
<tr>
<td>Sexual</td>
<td>400 IU IM</td>
<td>Single dose within 72 hours of last contact‡</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Within 7 days of exposure and at 1 and 6 months after first dose</td>
</tr>
</tbody>
</table>

* Percutaneous, ocular or mucous membrane exposure to blood or potentially blood contaminated secretion.
† The 1st dose can be given at the same time as HBIG, but should be administered at a separate site. Administration as soon as possible after exposure is preferred.
‡ There is limited evidence for efficacy if given within 14 days of contact: administration as soon as possible after exposure is preferred.

Previously vaccinated household contacts (without sexual contact or perinatal exposure who are assessed as having low risk for recent percutaneous, ocular or mucous membrane exposure) with test results:

- HBsAb <10 mIU/mL,
- anti-HBc negative and HBsAg negative

should be given a single booster dose (4th dose) of vaccine and retested for anti-HBs levels in 4 weeks (see Section 3.8).
6 Management of hepatitis B infection in primary care

Hepatitis B is a potentially lifelong condition affected by several lifestyle factors and other chronic diseases; the active involvement of the primary care provider is crucial.

6.1 Acute hepatitis B

6.1.1 Clinical features
- Symptoms commence 45-180 days after infection
- Symptoms may consist of: lethargy, nausea, vomiting, jaundice, right upper quadrant pain, rash and arthralgia
- A small proportion of people develop fulminant liver failure.

6.1.2 Diagnosis
- Transaminase enzymes (ALT/AST) are highly elevated (usually >10 times upper limit of normal)
- HBsAg and anti-HBc IgM are positive
- Over a 6 month period serology will evolve with anti-HBs and anti-HBc IgG appearing and HBsAg disappearing in 90-95% of adult cases
- If serology picture is unclear repeat after 4 weeks.

6.1.3 Notification
- Hepatitis B is a notifiable disease in the NT and is notifiable by both doctors and laboratories. All cases should be notified by contacting your local CDC office, particularly if the case is suspected to be newly acquired. Those previously notified (after 2004) do not need to be renotified (see Appendix 7 for definitions).

6.1.4 Contact tracing
- Contact tracing should be initiated by the clinician managing the patient (Section 5). If they are unwilling or unable to perform contact tracing themselves assistance from or referral to Clinic 34 is available.

Patients should be advised that:
- Acute HBV is highly infectious via unprotected sexual exposure, mucosal and parenteral contact
- They should inform all sexual, injecting equipment sharing and household contacts* who are exposed during the period from 2 weeks before onset of symptoms to seek testing and possible vaccination

* For practical purposes household contacts are defined as those who have spent more than 4 weeks of the last 6 months living in the case’s house (see Section 5.1).
6.1.5 **Clinical management**

- Regularly monitor prothrombin time, glucose, bilirubin and clinical signs of encephalopathy.
- Urgent referral to hospital after discussion with infectious diseases specialist if the person has an ALT>1000, an abnormal prothrombin time, clinical evidence of encephalopathy, is vomiting or is pregnant (see Appendix 2).

6.1.6 **Follow-up**

- Continue to monitor for signs of liver failure until acute illness resolves.
- Perform HBV serology at 6 months. If HBsAg remains positive manage as chronic hepatitis B infection.

6.2 **Chronic hepatitis B**

6.2.1 **Clinical features**

- Chronic hepatitis B is predominantly asymptomatic.
- In 20-30% of people persisting inflammation leads to progressive liver fibrosis, cirrhosis and increased risk of hepatocellular carcinoma.

6.2.2 **Diagnosis**

- HBsAg positive for more than 6 months.
- HBeAg indicates highly replicative infection, with greater risk of transmission.
- Occasionally people who are anti-HBc positive but lack both HBsAg and anti-HBs have ‘occult hepatitis B’. People with elevated ALT and the above serological pattern should be referred for specialist review (see below for pathway).

6.2.3 **Notification**

- Chronic hepatitis B is a notifiable disease in the NT and is notifiable by both doctors and laboratories. All cases should be notified by contacting your local CDC office, particularly if the case is suspected to be newly acquired. Those previously notified (after 2004) do not need to be renotified (see Appendix 7 for definitions).

6.2.4 **Contact tracing**

- Contact tracing should be initiated by the clinician managing the patient (see Section 5). If they are unwilling or unable to perform contact tracing themselves assistance or referral to Clinic 34 is available.

Patients should be advised that:

- Chronic HBV is transmitted by unprotected sexual exposure, mucosal and blood to blood contact through exposures such as sharing of contaminated equipment that penetrates the skin e.g. needles, tattoo equipment, body piercing equipment acupuncture equipment and razor blades.
They should inform all sexual, injecting equipment sharing and household contacts of the need for testing and possible vaccination.

If they are likely to have acquired the infection prior to adulthood, the potential benefits of advising their family, particularly their mother, should be discussed.

6.2.5 Clinical management

All people newly diagnosed with chronic HBV will need long term regular monitoring. They should be investigated at diagnosis and at least yearly thereafter to determine the need for referral to a specialist.

- Advice should be provided on the importance of safe alcohol use and maintenance of a normal body mass index (BMI)
- Test and vaccinate as required for hepatitis A virus. Hepatitis D testing is not recommended in the NT due to the current low prevalence.  

Perform HBV viral load for all pregnant women who are HBsAg positive. Women with a high HBV viral load (>10⁷ IU/mL) are at risk of transmission to the foetus in-utero and require urgent referral as described below.

Initial assessment

- Physical examination for signs of chronic liver disease
- The following tests:
  - Liver function test – repeat 3 times over 6 months, earlier if markedly abnormal
  - Full blood count, electrolytes, coagulation studies, iron studies, fasting blood glucose and lipids
  - Hepatitis C (and D virus serology if acquired overseas)
  - HBeAg, anti-HBe, HBV viral load (DNA level).

Include liver ultrasound scan if over 40 years OR over 30 years AND ANY OF unsafe alcohol use, HBV/HCV coinfection, HBV/HIV coinfection.

Monitoring

It is recommended that care plans should be set up for chronic HBV patients where there is a primary care database such as the Primary Care Information System (PCIS) or Communicare.

Chronic HBV patients require the following:

- Clinical examination,
- LFTs, HBV viral load,
- HBeAg (if baseline HBeAg positive)
  - 12 monthly if baseline ALT normal and at first visit during pregnancy.

* For practical purposes household contacts are defined as those who have spent more than 4 weeks of the last 6 months living in the case’s house (see Section 5).
6-monthly if ALT is raised or fluctuating

- Screening for hepatocellular carcinoma with 6-monthly serum alpha fetoprotein and liver ultrasound scan for:
  - All Indigenous people >50 years of age
  - People with proven or suspected cirrhosis
  - People with a 1st degree family history of hepatocellular cancer.

**Referral**

Chronic HBV patients with any of the following should be referred for specialist assessment:

- Consistently elevated ALT (> the upper normal limit)
- HBV DNA >2,000 IU/mL
- Known or suspected cirrhosis – 2 or more of: clinical signs, ultrasound signs, abnormal bilirubin/platelets/INR/albumin
- Receiving or planned to receive immunosuppression or other forms of immunocompromise (level 2 or above as defined in Appendix 3)
- Currently pregnant AND HBV viral load very high (>10^7 IU/mL) (see Appendix 2)
- Children with chronic hepatitis B (age under 16 years)
- Any patient where the primary care doctor feels further advice is required
- Hepatitis C or HIV co-infection
- Family history of hepatocellular carcinoma.

**6.3 Specialist referral**

For patients who meet the referral criteria and have had initial assessment performed refer to liver clinic at Royal Darwin (RDH) or Alice Springs Hospital (ASH). Some communities receive regular outreach liver clinics – check if this is the case before referring to RDH or ASH.
### 7 Appendix 1

#### Dates hepatitis B vaccine was introduced in the NT

<table>
<thead>
<tr>
<th>Date of introduction</th>
<th>Vaccine eligibility</th>
<th>Schedule of vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 1988</td>
<td>High risk infants</td>
<td>Birth, 1 month, 6 months</td>
</tr>
<tr>
<td>August 1990</td>
<td>All infants born on or after 1 August 1990</td>
<td>Birth, 2 months, 6 months</td>
</tr>
<tr>
<td>1993</td>
<td>All infants born on or after 1 August 1990</td>
<td>Birth, 1 month, 6 months (due to introduction of Hib vaccine)</td>
</tr>
<tr>
<td>1998/9 (Special vaccine program)</td>
<td>All children aged 6-16 years</td>
<td>0, 1, 6 month intervals (as part of a school based program)</td>
</tr>
<tr>
<td>May 2000</td>
<td>All infants born on or after 1 August 1990</td>
<td>Birth, 2 months, 4 months, 6 months (due to introduction of multivalent doses containing hepatitis B*)</td>
</tr>
</tbody>
</table>

* Hepatitis B vaccine has been available in differing multivalent vaccines used in the NT. They have included Infanrix–HepB (May 2000) Infanrix–Penta (November 2005) and Infanrix®Hexa (October 2009).
8 Appendix 2

Suggested pathway for management of pregnant women with HBV infection

- Screen all antenatal women for HBsAg and anti-HBc (GPs, remote communities, antenatal clinics, CARPA)

- **HBsAg -ve**
  - If HBeAb and HBsAb -ve
    - Offer HBV vaccination postpartum

- **HBsAg +ve**
  - Request HBeAg, anti-HBe, HBV DNA VL, LFT

  - **HBV DNA VL > 10,000,000 (10⁷) IU/mL OR ALT > 30 and HBV DNA VL > 2000 IU/mL**
    - Discuss with Liver Clinic doctor ASAP
    - Refer to Liver Clinic (see at 28-32 weeks)
    - Consider commencing antiviral (usually tenofovir) between 28-36 weeks
    - (the earlier the better)
    - Continue until 12 weeks post partum

  - **HBV DNA VL < 10,000,000 (10⁷) IU/mL AND ALT < 30**
    - No treatment received: LMO/remote clinic to perform yearly LFTs, HBeAg/AAb and HBV DNA VL
    - Refer to Liver Clinic if concerned regarding need to start treatment

- Give all infants HBIG and HBV vaccine at birth (in different sites within 12 hours of delivery). Notify RHG Infectious Disease of admission to ward

- **Follow-up of infants** at > 9 months of age (testing 3 to 12 months after final HBV vaccination) for HBsAg and anti-HBe (put alert on PCIS, Communicare or Jadecare).

  - **Follow up mothers treated with tenofovir** repeat HBVDNA VL and LFTs at delivery, 12 weeks post partum and then LFTs 2, 6, 12 and 24 weeks after tenofovir ceased.

- *Tenofovir and lamivudine are excreted in breast milk in very low concentrations and their safety has not been proven in breastfed infants. However, the benefit in this setting outweighs the negligible risk of harm to the infant.*
## 9 Appendix 3

### Risk levels of immunosuppression with regard to HBV reactivation

<table>
<thead>
<tr>
<th>Risk levels of immunosuppression</th>
<th>Level 3 – high risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Rituximab</td>
</tr>
<tr>
<td></td>
<td>• Allogeneic stem cell transplant</td>
</tr>
<tr>
<td></td>
<td>• Autologous stem cell transplant</td>
</tr>
<tr>
<td></td>
<td>• Chemotherapy for haematological malignancy</td>
</tr>
<tr>
<td></td>
<td>• High-dose chemotherapy for solid organ malignancy</td>
</tr>
<tr>
<td></td>
<td>• Immunosuppression for solid organ transplant, trans-arterial chemo-embolisation</td>
</tr>
<tr>
<td></td>
<td>(TACE) for hepatocellular carcinoma</td>
</tr>
<tr>
<td>Level 2 – moderate risk</td>
<td>• Methotrexate for autoimmune disease</td>
</tr>
<tr>
<td></td>
<td>• Cyclophosphamide</td>
</tr>
<tr>
<td></td>
<td>• Low dose chemotherapy for solid organ malignancy</td>
</tr>
<tr>
<td></td>
<td>• Glucocorticoids equivalent of ≥20mg/day prednisone or equivalent (children ≥0.5mg/kg/day up to 20mg) for &gt;14 days, high dose pulsed glucocorticoids with a total expected cumulative corticosteroid dose of the prednisone equivalent of 7mg/kg within one month</td>
</tr>
<tr>
<td></td>
<td>• Infliximab, ertanacept, adalimumab, golimumab, certolizumab</td>
</tr>
<tr>
<td></td>
<td>• Azathioprine</td>
</tr>
<tr>
<td></td>
<td>• Cyclosporin and tacrolimus use outside of the transplant setting</td>
</tr>
<tr>
<td>Level 1 – low risk</td>
<td>• Glucocorticoids &lt;20mg/day and/or &lt;14 days</td>
</tr>
<tr>
<td></td>
<td>• Hydroxychloroquine</td>
</tr>
<tr>
<td></td>
<td>• Leflunomide</td>
</tr>
</tbody>
</table>
## 10 Appendix 4

Serological, viral load and biochemical profiles of hepatitis B virus

<table>
<thead>
<tr>
<th></th>
<th>HBsAg</th>
<th>Anti-HBs</th>
<th>Anti-HBc (total)</th>
<th>Anti-HBcIgM</th>
<th>HBeAg</th>
<th>Anti-HBe</th>
<th>HBV viral load (IU/mL)</th>
<th>ALT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute HBV</strong></td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+/-</td>
<td>high</td>
<td>↑</td>
</tr>
<tr>
<td><strong>Natural HBV immunity (resolved infection)</strong></td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+/-</td>
<td>Absent N</td>
<td></td>
</tr>
<tr>
<td><strong>Vaccination</strong></td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Absent N</td>
<td></td>
</tr>
<tr>
<td><strong>Chronic HBeAg positive</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immune tolerance phase</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>&gt;20,000 IU/mL N</td>
<td></td>
</tr>
<tr>
<td>Immune clearance phase</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+/-</td>
<td>&gt;20,000 IU/mL (fluctuating) ↑</td>
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</tr>
<tr>
<td><strong>Chronic HBeAg negative</strong></td>
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<tr>
<td>Immune control phase</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>&lt;2,000 IU/mL* N</td>
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</tr>
<tr>
<td>Immune escape phase</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>&gt;2,000 IU/mL* ↑</td>
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</tr>
<tr>
<td><strong>Occult HBV</strong></td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+/-</td>
<td>Very low N</td>
<td></td>
</tr>
<tr>
<td><strong>Reactivation of HBV</strong></td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+/-</td>
<td>+</td>
<td>+/-</td>
<td>&gt;20,000 IU/mL ↑</td>
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</tr>
</tbody>
</table>

+ = positive, - = negative, N = normal, ↑ = elevated.

*HBV viral load cut off levels may change in the future.
11 Appendix 5

HM8 Immunisation record

<table>
<thead>
<tr>
<th>Vaccine - Batch No.</th>
<th>Date</th>
<th>Signature</th>
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<tbody>
<tr>
<td>Human Papillomavirus</td>
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<tr>
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<td>3. .......................... / / / / /</td>
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</tr>
<tr>
<td>Adult Diphtheria Tetanus (ADT)</td>
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<td>3. .......................... / / / / /</td>
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<tr>
<td>Influenza (specify if adult or paediatric)</td>
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<td>3. .......................... / / / / /</td>
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<tr>
<td>Other (specify)</td>
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</tr>
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</table>

Contact phone numbers
Northern Territory Government Northern Territory Government 1300 071 811
NT Immunisation Hotline 1800 672 002
DoH Centre for Disease Control, Darwin 0822 06344
Centrelink (maternity and family benefits) 136 150

This is an important record!
Keep it in a safe place and bring it with you when you attend a vaccination clinic or go into hospital.

Vaccine - Batch No. | Date | Signature
<table>
<thead>
<tr>
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<tbody>
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<td>Hepatitis B Immunoglobulin</td>
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<tr>
<td>BCG</td>
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</tr>
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<td>3. .......................... / / / / /</td>
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<tr>
<td>Pneumococcal conjugate (Prevenar)</td>
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<td>5. .......................... / / / / /</td>
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<td>Rotavirus (Rotarix)</td>
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<td>Haemophilus influenzae type b-Meningococcal C (Mening)</td>
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<tr>
<td>Measles mumps rubella (Prontix) or (M-M-RIII)</td>
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<tr>
<td>Measles mumps rubella varicella (Prontix - Tetra)</td>
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<td>5. .......................... / / / / /</td>
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<tr>
<td>Hepatitis A (VAQTA)</td>
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<tr>
<td>Varicella (Varilrix) or (Varivax)</td>
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<tr>
<td>Pneumococcal polysaccharide (Pneumovax)</td>
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<tr>
<td>DTPa-IPV (Infanrix IPV)</td>
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<td>1. .......................... / / / / /</td>
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<tr>
<td>Adult Diphtheria Tetanus Pertussis (Boostrix)</td>
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<tr>
<td>Hepatitis B (specify if adult or paediatric)</td>
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</table>
12 Appendix 6

Hepatitis B serology advice – anti-HBs negative

**Background:** This advice is provided due to enquiries about what to do when hepatitis B screening reveals anti-HBs <10 in people who are immunised and have negative HbsAg and anti-HBc.

This guidance is only for those people who were immunised several years ago. Different advice is necessary for those who have been recently vaccinated.

**Guidance from CDC:**

For those people who have been fully immunised¹ and on screening are anti-HBs negative² (i.e. anti-HBs <10) then the action is to do nothing, unless they fall into a high risk category.³

For those in a high risk category, who have not previously been anti-HBs positive, give a booster and check anti-HBs in 1 month.

**Explanation:** anti-HBs is a poor test of post-vaccination immunity many years post-vaccination. If someone has been fully immunised, immunity is likely to be present in spite of undetectable levels of antibody, because antibody levels naturally wane over time.

People in high risk categories should be shown to be immune by testing between 4 and 8 weeks of completion of the course. If this has not been done and they are anti-HBs negative many years later then a booster will cause anti-HBs to rise to detectable levels to demonstrate immunity.

1. Fully immunised means having had at least 3 doses with the 3rd dose being given after 24 weeks of age.
2. Assuming also anti-HBc and HbsAg negative
3. High risk categories are:
   - Healthcare worker
   - Those at risk of complicated disease: e.g. liver disease, immunosuppressed
   - Haemodialysis patients
   - Sexual partners and household contacts of Hep B positive individuals.
13 Appendix 7

Notification case definitions

Hepatitis B Chronic

Reporting

Only confirmed cases should be notified.

Confirmed case

A confirmed case requires:

1. laboratory definitive evidence

Laboratory definitive evidence

Detection of hepatitis B surface antigen (HBsAg), or hepatitis B virus by nucleic acid testing, in a patient with prior evidence of hepatitis B virus infection greater than six months ago.¹ ²

Note

1. The case should not meet the criteria for newly acquired hepatitis B.
2. If a case fulfils the definition of “chronic” based on old results which are not on the database, these old results should not be entered with the new entry, but appended and filed with the hard copy.
3. Once a case is classified as unspecified or chronic it need not be changed unless the original classification was incorrect.
4. New results need not be added, unless there is further information to be obtained – e.g. genotype.
5. If the case was previously reported as 'newly acquired’ then a new entry as “Hep B – chronic” should be made.

Hepatitis B – Newly acquired

Reporting

Only confirmed cases should be notified.

Confirmed case

A confirmed case requires laboratory definitive evidence only.

Laboratory definitive evidence

1. Detection of hepatitis B surface antigen (HBsAg) in a patient shown to be negative within the last 24 months

OR

2. Detection of HBsAg and IgM to hepatitis B core antigen, in the absence of prior evidence of hepatitis B virus infection

OR

3. Detection of hepatitis B virus by nucleic acid testing, and IgM to hepatitis B core antigen, in the absence of prior evidence of hepatitis B virus infection.

Hepatitis B - Unspecified

Reporting

Only confirmed cases should be notified.

Confirmed case

A confirmed case requires laboratory definitive evidence AND that the case does not meet any of the criteria for a newly acquired case.
Laboratory definitive evidence

Detection of hepatitis B surface antigen (HBsAg), or hepatitis B virus by nucleic acid testing, in a patient with no prior evidence of hepatitis B virus infection.

Note

The case should not meet the criteria for newly acquired or chronic hepatitis B.
14 References


