

Hepatitis B

Te Mana Ora protocol

This protocol is based on the Ministry of Health's <u>Communicable Disease Control Manual¹</u> and <u>Immunisation Handbook²</u> hepatitis B chapters. Te Mana Ora-specific content is in green.

Recently updated content is in blue.

Protocol users should **document** their response to **action points**, marked throughout with this arrow.

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1. Associated material

Te Whatu Ora Waitaha Canterbury Māori Health policy

Te Whatu Ora Waitaha Canterbury Te Reo policy

Te Whatu Ora Waitaha Canterbury Tikanga policy

<u>Te Whatu Ora Waitaha Canterbury Interpreter procedure | Te Mana Ora Interpreting and Written Translation procedure</u>

Te Whatu Ora Waitaha Canterbury Privacy/Nohotapu policy

Te Mana Ora procedures, forms, checklists, orders, letters, etc and reference documents from the Ministry of Health and other agencies are in

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Case report form:

K:\CFS\ProtectionTeam\FinalDocs\NotifiableConditions\HepatitisB

Fact/information sheet or Ministry online information:

https://www.health.govt.nz/your-health/conditions-and-treatments/diseases-and-illnesses/hepatitis-b

https://healthed.govt.nz/products/hepatitis-b-and-c



2. The Illness

Global burden of disease

In 2015, based on serological data, around 3.5 percent of the general population globally were infected with HBV and more than 250 million people were estimated to have chronic infection and these people remain at risk of developing cirrhosis and hepatocellular carcinoma. More than 90 percent of individuals with chronic HBV resided in the Asia–Pacific region, where most countries have high prevalence rates of HBV, and more than 99 percent of HBV-infected people in this region acquired infection through vertical transmission from their mother (usually at the time of delivery) or in early childhood. The introduction of universal childhood HBV immunisation has changed the epidemiology of chronic infection in many countries, but it will be several decades (one to two human generations) before the full benefits are realised.

Epidemiology in Aotearoa New Zealand²

Before the introduction of HBV immunisation in New Zealand in 1988 HBV transmission was common among preschool and school-aged children. The exact mode of transmission is uncertain, but is thought to be related to close contact. In the eastern Bay of Plenty region almost half of the population were infected by age 15 years.

Hepatitis B notifications have declined from 609 cases in 1984 to 28 cases in 2019 (see Figure 1). While difficult to quantify accurately, the introduction of universal infant immunisation in 1988 has contributed to the dramatic decline in the number of newly notified cases of HBV infection.

Number of notifications 160 140 120 100 80 60 40 20 0 1997 1999 2001 2003 2005 2007 2009 2011 2013 2015 2017 2019 Report year

Figure 1: Notifications of hepatitis B, 1997-2019

Source: ESR

Risk factors for acute hepatitis B in New Zealand include overseas travel and sexual contact, as well as household contact with a chronic carrier. An estimated 1–2 percent of the New Zealand population are carriers of hepatitis B. Chronic hepatitis B carrier status is currently not notifiable; notification rates do not describe the burden of chronic HBV infections.

The HBV notification rate in 2019 was 0.6 per 100,000 population (28 cases). Ethnicity was recorded for all cases. The Māori (1.3 per 100,000) ethnic group had the highest hepatitis B notification rate followed by the Asian (0.7 per 100,000) ethnic group.



Te Mana Ora cases: last ten years

Table 1: Te Mana Ora cases by district, last 10 years

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Waitaha/ Canterbury	4	8	3	4	2	3	4			
Waitaha ki te Toka/ South Canterbury						1		1		
Te Tai o Poutini/ West Coast	1									
TOTAL	5	8	3	4	2	4	4	1	0	0

Table 2: Te Mana Ora cases by ethnicity, last 10 years

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
European	2	4	1	4	1	2	2	1		
Māori	1	1	1		1	1	1			
Pacific	2					1				
Asian		1					1			
Other		1								
Unknown		1	1							
TOTAL	5	8	3	4	2	4	4	1		

Clinical description

The clinical manifestations of acute hepatitis B infection in adults range in severity from **minimal** symptoms to **fulminant hepatitis** (in less than 1 percent of cases). Adults may experience the insidious onset of **fever**, **malaise**, **abdominal discomfort** and **anorexia** with **jaundice** or **elevated serum aminotransferase** levels.

Acute hepatitis B infection in the first few months of life seldom causes clinical disease, and symptoms or signs are **less common in children** than in adults.

Virology

The hepatitis B virus (HBV) is a partially double-stranded DNA virus belonging to the Hepadnaviridae family. Three major subunits make up the structural components:

- the HBV genome, a small, circular, partially double-stranded DNA molecule, in association with a polymerase enzyme
- the nucleocapsid core, which surrounds the genome and consists of core protein (hepatitis B core antigen, HBcAg)
- the outer lipoprotein envelope, which contains the hepatitis B surface antigen (HBsAg).

The genome has four genes (S, C, X and P). Both the core nucleocapsid protein (HBcAg) and the 'early' protein (which makes HBeAg) are translated from the C gene. HBcAg is essential for viral packaging and is an integral part of the nucleocapsid. HBeAg is a soluble protein that is not part of the virus particle. Detection of HBeAg in the serum is correlated with viral replication and is a marker for severe disease. It is most commonly found in those with acute hepatitis B and those with chronic HBV infection with high viral load.

Incubation

45–180 days, commonly **60–90** days



Transmission

Many body substances and tissues (such as **blood**, **semen** and **vaginal fluids**) are capable of transmitting hepatitis B, via percutaneous (intravenous, intramuscular, subcutaneous or across broken skin) or permucosal exposure. This includes transmission through sexual contact, body piercing and tattooing.

Perinatal mother-to-infant transmission and transmission through occupational exposure to infected blood is now uncommon in New Zealand.

Communicability

The case is potentially infective **2–3 weeks before the onset** of symptoms, during the clinical disease and usually for **2–3 months after acute infection** or as long as HBsAg. continues to be present in blood.

If a person **continues to have HBsAg** present in their blood, they are a **carrier**; defined as having two positive HBsAg tests taken at least 6 months apart. Carriers of hepatitis B continue to be **infectious**. Those who are both HBsAg and **HBeAg** (HB early antigen) positive have the highest infectivity. The carrier state may follow asymptomatic infection and is most common after perinatal infection, infection in infancy, or in those with immunodeficiency.

Vaccination

New Zealand is a country with a low overall prevalence of hepatitis B carriage, but it contains certain populations with high prevalence. All pregnant women and high-risk groups should be screened for chronic HBV infection.

Hepatitis B **vaccine efficacy** is 85–95 percent in high risk groups, though likely to be lower in older individuals and those with immunocompromise. Protection is expected to be lifelong and boosters are not required.

Vaccination is **funded** for infants (at ages 6 weeks, 3 months and 5 months: DTaP-IPV-HepB/Hib), and for individuals with eligible conditions or close household contacts of infected individuals (HepB). Infants born to HBsAg-positive mothers should receive HepB vaccine plus HBIG at birth, then the usual childhood schedule, with serological testing at age 9 months (anti-HBs and HBsAg).

Vaccination is **recommended but not funded** for those with increased risk from occupational or sexual exposure to body fluids and faeces, or receiving regular blood products, and those with developmental disability, current or prior injectable drug users, prison inmates, and travellers to and from high-prevalence countries.

3. Notification

Attending medical practitioners and laboratories must notify the local medical officer of health of an acute illness, not the carrier status.

4. Case definition

Clinical criteria

Common symptoms of hepatitis B are **fever**, **malaise**, **abdominal discomfort** and **anorexia** with **jaundice** or **elevated serum aminotransferase levels**.

Case classification

Under investigation: A case that has been notified, but information is not yet available to classify it as probable or confirmed.

Probable: A clinically compatible illness with a positive HBsAg (over 12 months of age).

Confirmed: A clinically compatible illness that is laboratory confirmed (see laboratory criteria below, including positive HBsAg under 12 months of age).

Not a case: A case that has been investigated and subsequently found not to meet the case definition.

Only acute hepatitis B is notifiable. The chronic carrier state is not notifiable (a chronic carrier is defined as having two positive HBsAg tests taken at least 6 months apart). The only way to distinguish acute HBV infection from acute-on chronic hepatitis B is through previous documentation of HBV infection. For management see Hepatitis B carriers section.



5. Laboratory testing

Laboratory confirmation requires at least one of the following:

- HBsAg positive in an infant aged under 12 months
- change from HBsAg negative to HBsAg positive within a 12-month period (if testing is performed at the same laboratory and the cumulative history is readily available within the laboratory information systems)
- anti-HBcore IgM reactive (unless HBsAg positive more than 6 months ago and the history is readily available in laboratory information systems)
- detection of hepatitis B virus (HBV) nucleic acid.

For interpretation of hepatitis B serology see Error! Not a valid bookmark self-reference..

Table 1: Interpretation of hepatitis B serology

	Serologic			Interpretation
HBsAg	Total anti-HBc	lgM anti-HBc	Anti-HBs	
-	_	-	_	Never infected
+	-	-	-	Early acute infection; transient (up to 18 days) after vaccination
+	+	+	-	Acute infection
_	+	+	+ or –	Acute resolving infection
_	+	-	+	Recovered from past infection and is immune
+	+	-	_	Chronic infection ^a
_	-	-	+	Immune if ≥10 IU/L vaccinated or natural infection

Key: Anti-HBc = antibody to hepatitis B core antigen; anti-HBs = antibody to hepatitis B surface antigen (HBsAq); IgM = immunoglobulin M; + = positive test result; - = negative test result.

a HBeAg positive (HBeAg+) correlates with high viral load and increased risk of transmission; HBeAg negative (HBeAg-) correlates with lower viral load and reduced risk of developing cirrhosis or cancer.

Adapted from: Van Damme P, Ward J, Shouval D, et al. 2018. Hepatitis B vaccines. In: Plotkin SA, Orenstein WA, Offit PA (eds). *Plotkin's Vaccines* (7th edition). Philadelphia, US: Elsevier. Table 25.1.

Cultural and social context

Cultural, social, work and home environments affect any person's risk of contracting a communicable disease, the likely impact of that disease on them, and their likelihood of passing the infection on others. Keep these factors in mind at every point of your investigation and follow-up.

- Request an interpreter if needed.
- **Consider** the potential impact of cultural, social, work or home factors on a person or family's ability or willingness to provide information and/or follow public health advice.
- **Tailor your advice** to the situation.
- Seek advice yourself if unsure. Talk to:
 - Te Mana Ora's Communicable Diseases Team Leader for advice on community and primary care support people or agencies.
 - Ngā Ratonga Hauora Māori for Māori patients at Christchurch Hospital or Christchurch Women's hospital.
- If appropriate, and with the case and/or contact's permission, seek the **assistance** of family or other community members, community leaders, and/or support agencies if required.



7. Management of case

Investigation

- Nurses action during **office hours**. Does not require HPO follow-up or after-hours response. In South Canterbury and West Coast, the Public Health Nurses follow up these notifications.
- Obtain a history of possible risk factors including:
 - o overseas travel
 - o body piercing (including needles, acupuncture or tattooing)
 - sharing razor blades
 - o infectious sexual contact (heterosexual or homosexual)
 - o household contact
 - o being bitten by someone
 - o sharing of drug-injecting equipment
 - o occupational exposure (including needle stick injury)
 - o occupational exposure to blood or blood products
 - working in high-risk occupational settings such as laboratory, mortuary, ambulance or police work or employment in facilities for the mentally disabled
 - residence in a facility for the mentally disabled
 - accidental exposure of eyes, mucous membranes or a wound to the blood of another person
 - o any medical procedure, transfusion of blood or blood products, or dialysis
 - o any dental procedure
 - any record of incarceration.
 - o if the case is an infant check the hepatitis B status of the mother
- Also obtain a history of vaccination and recent sexual and household contacts.
- Ensure full **hepatitis B serological testing** of the case (including HBeAg and anti-HBe) and consider testing for **other** blood-borne virus infections.
- Advise the case and primary health care doctor to **repeat HBsAg testing after 6 months** to identify the chronic carrier status.
- Although **chronic carriers** are not notifiable, consider **referral back to the primary health care doctor** regarding follow-up for case care and testing and immunisation of contacts. See 'Hepatitis B carriers' below.
- Only acute cases are entered on Episury

Restriction

Cases acutely infected with hepatitis B **must not donate blood**. Donors contracting acute hepatitis B may be acceptable 1 year after the acute episode providing there was clearance of HBsAg within 6 months and the New Zealand Blood Service medical officer has given medical clearance.

Employers must assess infected **health care workers** to determine whether any work restrictions are indicated (for example, regarding exposure-prone procedures and adoption of universal precautions).

Treatment

Antivirals are used in fulminant disease otherwise there is currently no specific treatment for acute hepatitis B other than supportive treatment.

Counselling

- Advise the case and their caregivers of the nature of the infection and its mode of transmission. For example, advise the case to:
 - o not share drug-injecting equipment, razors or toothbrushes
 - o use safer sex practices
 - avoid exposing others to their blood or other body fluids (including not donating blood or semen or registering as an organ donor)
 - o **inform health care workers** (including dentists) of their infectious status.
 - o avoid hepatotoxic agents including alcohol and recreational drugs
 - o consider **vaccination for HAV** for those non-immune





Post standard letter and hepatitis B fact sheet to case. https://www.health.govt.nz/your-health/conditions-and-treatments/diseases-and-illnesses/hepatitis-bhttps://healthed.govt.nz/products/hepatitis-b-and-c

Chronic carriers need ongoing advice on follow-up care from GP (or ask GP to refer to the Hepatitis A Foundation of NZ) and precautions against transmission.

8. Management of contacts

Definition

Contacts include all **household members** and people who have had **unprotected relevant contact** (for example, perinatal, sexual or percutaneous, including sharing drug-injecting equipment or sharps injury, or mucosal exposure) with a case **in the 3 weeks before onset of illness or during the subsequent period of communicability**.

Investigation

➤ In conjunction with the case **identify contacts** and arrange for them to have **serology** and **referral to a GP for immunoglobulin and vaccination if appropriate.** Results of the serology should be sent to both Te Mana Ora and the contact's primary health care doctor.

All contacts require serological testing for HbsAg, anti-HBs and anti-HBc, IgM and IgG. Public health should liaise with the contact's primary health care doctor to determine who will do this. Results should be sent to both public health and the contact's primary health care doctor.

Interpretation of results of serology

- 1. If HBsAg negative + anti-HBs negative + anti-HBc negative, the contact is susceptible and vaccination is required.
- 2. If HBsAg negative + anti-HBs negative + anti-HBc positive, the contact may still be susceptible and vaccination is required because the results may indicate (amongst other possibilities) a false positive anti-HBc or, if an infant, maternal antibody.
- 3. If the contact is HBsAg positive, ensure their primary health care doctor is aware of this and that follow-up is arranged.

No post-exposure prophylaxis is required for contacts who have had previous hepatitis B infection, or have a current protective level of antibodies from hepatitis B vaccination, or have documented previous seroconversion from hepatitis B vaccination to a protective level (see the Immunisation Handbook for more information).

Any difficulties with interpreting serological results for cases and contacts should be discussed with an infectious diseases physician or the laboratory.

Restriction

As for a case, at least until results of initial (and any necessary follow-up) blood tests are known.

Prophylaxis

Immunisation Handbook.

See HBIG is given at the same time as the vaccine but at a different site. Table 3 sets out the required dose by age group.

For details regarding obtaining immunoglobulin and administration refer GP to HealthPathways For details of hepatitis B schedules for newborn infants of carrier mothers, and also catch up, see the

Table 2.

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For details regarding obtaining immunoglobulin and administration refer GP to HealthPathways

For details of hepatitis B schedules for newborn infants of carrier mothers, and also catch up, see the <u>Immunisation Handbook</u>.



Table 2: Management of contacts of hepatitis B cases - summary

Contact	Serological testing of contact (HbsAg, anti- HBs, anti-HBc IgM and IgG)	Immunoglobulin (if within 7 days of onset of case's symptoms)	Immunisation
Any sexual contact, including protected sex	Yes	Yes, immediately after blood taken	Yes, immediately after blood taken
Household, mucosal or percutaneous	Yes	Yes, if serology negative	Yes, if serology negative
Other	Yes	No	Yes, if serology negative

Table 3: HBV immunoglobulin doses for contacts of hepatitis B cases, by age group

Age	HBIG dose (IU)
Neonates under 1 month	100
1 month-4 years	200
5-9 years	300
10 years and over	400

Counselling

Advise all contacts of the nature of the infection and its mode of transmission, and to seek early medical attention if symptoms develop.

9. Other control measures

Identification of source

➤ Investigate potential relation to **body piercing and/or tattooing or health care events.** If the case could be transfusion-related, contact the New Zealand Blood Service.

Disinfection

Hepatitis B virus is stable on environmental surfaces (for example, inanimate objects) for at least 7 days.

Clean equipment and surfaces potentially contaminated with blood or body fluids. See Communicable Disease Control Manual Appendix 1: Disinfection.



10. Hepatitis B carriers

Although hepatitis B carriage is not notifiable, health care professionals looking after such carriers should ensure that close contacts have been offered immunisation and should provide carriers with appropriate information on how to protect others and how to look after themselves, with a referral if required.

The Ministry of Health contracts the Hepatitis Foundation of NZ to provide a **hepatitis B surveillance programme** to eligible carriers. This programme provides regular hepatitis serology and liver function testing, enabling timely referral in cases of early evidence of liver disease and/or cancer.

HBIG can be considered for susceptible household, sexual, percutaneous and mucosal contacts, particularly if the exposure is of recent limited duration and highly significant (for example, exposure to a significant volume of infected blood) and the source case is HBeAg positive, has high serum levels of HBV DNA or the sexual contact was non-consensual.

Indications for hepatitis B vaccination are the same as for contacts of acute hepatitis B cases.

11. Reporting

- Enter case details on EpiSurv.
- **Document** your response to each **action point** (marked with this arrow) in this protocol
- If an **outbreak** occurs, contact the NPHS Protection Directorate, 0800GETMOH CD option, and outbreak liaison staff at ESR, and complete the Outbreak Report Form.

12. References and further information

- 1. Ministry of Health, *Communicable Disease Control Manual*. 2019, Ministry of Health: Wellington. https://www.health.govt.nz/our-work/diseases-and-conditions/communicable-disease-control-manual/hepatitis-b
- 2. Ministry of Health. Immunisation Handbook 2020. Chapter 9 Hepatitis B. https://www.health.govt.nz/our-work/immunisation-handbook-2020/9-hepatitis-b



13. Document Control

Protocol review task	Responsibility	Date completed + version no.
Advise team, Quality Coordinator (QC) of review (and planned timeframes).	Public Health Specialist (PHS)	V4, 01/08/2023
Open the protocol in EDMS Owner's view, ensure it is based on the current template, remove any blue font formatting (indicating new content for the previous version), and turn on "track changes".	PHS	V4, 01/09/2023
Review Manatū Hauora Ministry of Health (MoH) advice, literature, other protocols, and write draft update: full revision for v4, in new protocol forma. t.	PHS	V4, 01/09/2024
Update Fact/ information sheet as necessary (or source the URL link from MoH website).	PHS	n/a
Start an EDMS review workflow of draft version to pre-set document members – MOsH, CD, Team Leader, and HPO for feedback. (Check members are correct before starting workflow. If not, contact QC to update.)	PHS	V4, 01/12/2023
Incorporate feedback and update draft(s) further as required.	PHS	V4, 27/02/2024
Start an EDMS approval/ publishing workflow of final version to Clinical Director (Authoriser).	PHS	V4, 27/02/2024
Clinical Director approval recorded in EDMS.	Clinical Director (CD)	V4, 4/03/2024
Document Controller (A.K.A. QC) receives EDMS notification of CD approval, and completes the following processes: > Document control tasks within document, incl. header, footer and formatting.	Quality Coordinator (QC)	V4, 4/03/2024
 EDMS document properties/ metadata updates. Checks and updates hyperlinks on <u>Te Mana Ora policies and procedures site</u>. Creates .pdf (for external link), and saves to CFS folder: Protocols - Y:\CFS\Quality\Archive\Protection\IntranetPROTOCOLS. 		
 New or reviewed document is uploaded to: Protocols: Surveillance (PHU server) website, and Microsoft Teams on-call documentation group. 		
 Fact/information sheets (where applicable) are checked for validity: Te Mana Ora CPH website, or MoH website. 		
Update paper copies as required (on-call folder/ vehicle).	Health Protection Officer (HPO)	V4, 4/03/2024
Advise operational/ district staff of update, summarising any substantial changes (text highlighted in blue font in document).	QC, HPO, or Team Leader	V4, 4/03/2024
Once process finalised, move any original draft documents saved in CFS locations to: Y:\CFS\Quality\Archive\Protection\ComDisProtocolsArchive	QC	V4, 4/03/2024
Minor update notes: V4, new format, rull review in new format		V4, 4/03/2024