



# Hepatitis B infection control in haemodialysis centres

A Victorian Renal Clinical Network consensus  
document



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## Definitions

Bloodborne virus (BBV)	Viruses carried in the human blood stream
CKD	chronic kidney disease
HBV	hepatitis B virus
HBVcAb	hepatitis B core antibody If positive it is an indication that the patient has had a previous hepatitis B infection
HBVsAb	hepatitis B surface antibody A marker for immunity to hepatitis B from either past infection or immunisation
HBVsAg	hepatitis B surface antigen If detected it is a marker of active viral replication in hepatitis B infection This may be present in either acute or chronic hepatitis B
HBV DNA	Polymerase chain reaction amplified DNA sequences allowing detection of lower levels of HBV viral replication than can be detected using serological testing
Standard precautions	Standard precautions are the work practices required to achieve a basic level of infection prevention and control. The use of standard precautions aims to minimise and, where possible, eliminate the risk of transmission of infection, particularly those caused by bloodborne viruses. Standard precautions are defined in the <i>Australian guidelines for the prevention and control of infection in healthcare</i> (1).
Transmission-based precautions	The precautions applied when the use of standard precautions alone are insufficient to prevent transmission of an infection or organism. The precautions applied are based on the mode of transmission. Transmission-based precautions are defined in the <i>Australian guidelines for the prevention and control of infection in healthcare</i> (1).
Personal protective equipment (PPE)	May include gloves, gown, mask, eye protection

# Purpose and scope

This document outlines the management of the hepatitis B virus (HBV) in haemodialysis units and has been written in response to an HBV transmission event that occurred between patients who attended the same dialysis unit in 2014.

The Victorian Renal Clinical Network has formulated this consensus document after reviewing existing hepatitis B policies from dialysis hub units in Victoria and discussion with stakeholders including communicable disease prevention and infection control teams and virologists. It extends the small section related to HBV in the guideline published by the Department of Human Services (now the Department of Health and Human Services) in 2006 (2) entitled *Infection prevention in the satellite haemodialysis setting*, which was removed from the website in about 2012.

A Caring for Australians with Renal Impairment (CARI) working group is looking at infection within dialysis units, and this group has a remit to deliver a guideline in the near future.

This HBV consensus document has been approved by the Victorian Renal Clinical Network leadership group and aims to reduce variation in clinical practice across the state, and provide a reference for satellite and affiliated services until such time as the CARI guidelines are updated in this area. This document makes reference and is congruent with a number of other Victorian and Australian policy documents.

National guidelines produced by Communicable Diseases Network Australia advise that:

The health care system should have an effective infection control strategy and provide a safe working environment that minimizes the risk of a sharps injury or exposure to body fluids, secretions and excretions and prevents the transmission of infections from person to person within the health care setting (3).

Strategies for preventing all infectious disease transmission in Victoria relies on:

- the effective implementation of standard precautions
- the promotion of home therapies (where exposure events are far less likely)
- renal transplantation where possible (negating dialysis requirement).

This means that the transmission of hepatitis B virus in or near dialysis units is a very rare event, and renal units are generally very safe places to receive care. Thus, many question the necessity for a different policy for HBV-positive patients, and opinion varies across the state about the necessity to formally isolate patients with a bloodborne virus (BBV). There is no doubt that in the 1970–80s, when HBV was more prevalent, there was a lower incidence of HBV infection in those units that isolated positive patients (4). Yet, much of this success may be related to other changes in practice and the introduction of standard precautions. Haemodialysis and haemodiafiltration are not classed as exposure-prone procedures (3).

Yet, there has been a recent case where transmission unequivocally occurred between patients attending the same dialysis unit, and while there appeared to be no breach in standard precautions identified by a review, this speaks to the highly infectious nature of the virus particles. Potentially also important is the inability to control inadvertent blood spills from patient-managed dialysis access such as an unintentional spill from a bleeding fistula after dialysis that goes unrecognised or unreported.

Thus, isolating HBV-positive patients should remain the preferred option where patients are known to be heavily viraemic (for example, HBVeAg positive or who have detectable circulating viral DNA). However, local circumstances including the availability of isolation facilities, resources and care teams, as well as potentially detrimental effects on the psychological wellbeing of patients, may dictate how patients with

HBV are managed. Patients identified as having HBV should undergo individual risk assessment, and a written record of the circumstances of dialysis should be kept.

Thus, this guideline proposal constitutes practical suggestions that aim to strike a balance between practicality and risk mitigation for a rare circumstance.

As well as HBV, there are a number of other known BBV that may be potentially pathogenic (such as hepatitis C and human immunodeficiency virus), plus other viruses for which there may not yet be routine testing. This is why it is vital that any blood spill or contamination is rapidly dealt with, and why all patients should be considered potentially infective, mandating standard precautions (1).

## Hepatitis B virus

The hepatitis B virus is a bloodborne DNA virus but can also be found in other body fluids such as semen and vaginal secretions. Body fluids, such as urine, faeces, tears and vomit, also contain the virus but usually carry a far lower risk of transmission. The incubation period for HBV is 45–160 days, and exposure can lead to an acute hepatitis or an asymptomatic chronic infection. The incidence of viral transmission in renal units has declined in recent years but can, and does, still occur (5). HBV can survive outside the body on surfaces for at least seven days (6) and still be capable of causing infection (7). Haemodialysis patients are considered immunocompromised and are more susceptible to infection. The most common mode of transmission among patients has been found to involve *sharing equipment* between patients (8, 9).

Healthcare workers (HCW) are expected to protect the health and safety of their patients and their colleagues, and this includes a requirement to prevent transmission from HCW to patients, from patients to HCW and between patients. Thus all HCW are strongly encouraged to undergo testing for BBV, and treatment if required (3).

It is recommended that 'all HCWs should be vaccinated against ... HBV if they have no documented evidence of pre-existing immunity (from natural infection or prior vaccination)' (3).

Vaccination is effective in more than 93 per cent of HCW after three doses of the vaccine (10). HCW who do not respond by developing an adequate antibody response should know their status so they may consider more involved vaccination regimens (such as intradermal vaccination) (11) or avoid known high-risk situations (such as dialysing a heavily viraemic patient). They should also be aware of the post-exposure prophylactic measures that can be used in the event of an exposure (12).

HBV is a group B notifiable disease and must be reported within five days of discovery at:

<https://www2.health.vic.gov.au/public-health/infectious-diseases/notify-condition-now>.



# 1 General policy statements

- 1.1 All units must have, and be familiar with, a written HBV policy (which may be this HBV consensus document).
- 1.2 Standard precautions must be practised by all staff for all patients regardless of viral status.
- 1.3 Machine cleaning in accordance with the manufacturer's guidelines must occur between patient sessions of dialysis and must be to the required standard. This includes standard heat disinfection and a full manual clean after every dialysis, which includes a full wipe down of all external surfaces.
- 1.4 All blood spills must be dealt with promptly in accordance with local policy, and personal protective equipment (PPE) standards must be adhered to (1).
- 1.5 The serial number of every machine should be noted (usually on the dialysis run chart) for every patient on every dialysis session so that contact tracing can occur should problems arise.
- 1.6 All HBVsAg positive or HBV DNA positive haemodialysis patients should have been offered an opinion from an infectious diseases physician and or a hepatologist.

## 2 Staff

- 2.1 The *Australian national guidelines* (3) state that 'HCWs are expected to protect the health and safety of their patients. This obligation includes preventing transmission of ... BBVs from themselves to their patients'.
- 2.2 Of equal importance is the need to prevent transmission from patients to HCW. Haemodialysis HCW have a greater chance of contact with blood and/or body substances from haemodialysis patients than most other HCW.
- 2.3 All staff must take personal responsibility for their own safety by knowing their vaccination history and HBsAb status.
- 2.4 Anyone working on a dialysis unit should be offered vaccination against hepatitis B if they do not have prior immunity.
- 2.5 Pre-employment screening and assessment of immunisation requirements should be undertaken when staff commence employment, and the employer should maintain a record of these results (1).
- 2.6 Staff should maintain a personal immunisation record (1).
- 2.7 Once a staff member has achieved an HBVsAb level > 10 IU/mL no further vaccination or testing is needed (unless there is concern over immune-competence) (1).
- 2.8 If staff fail to seroconvert after two full vaccination courses, they should be counselled about the risks of HBV transmission and/or offered alternative vaccination strategies such as subcutaneous or novel adjuvant intradermal vaccination if available (11).
- 2.9 Staff who have never attained an HBVsAb level > 10 IU/mL should not knowingly look after patients on dialysis known to have circulating HBV DNA.
- 2.10 Staff must take individual responsibility for informing their renal unit if they do not have protective immunity against hepatitis B (they have never had an HBVsAb level  $\geq$  10). Where a staff member

without immunity informs a unit of this fact, it is the responsibility of the renal unit to ensure that such a staff member does not knowingly look after a patient who is known to be viraemic (viral load detectable by HBV DNA polymerase chain reaction) on dialysis. This must not prejudice the working opportunities of such a staff member, and compliance with equal employment opportunity legislation is paramount.

- 2.11 Staff looking after patients with detectable HBV DNA should not simultaneously look after haemodialysis patients who have no demonstrable immunity to HBV (any patient with HBVsAb level < 10) during the same dialysis shift. If resources are unavailable locally to avoid this, then equipment and PPE must be provided at each dialysis space and must not be taken from one patient to the next.
- 2.12 Staff without protective immunity should be advised of the importance of post-exposure prophylaxis with hepatitis B immunoglobulin (HBIG) within 72 hours of an exposure event (13).
- 2.13 Staff should be aware of the viral status of their patient after the last routine screening, and this information should be readily available at each dialysis session if needed.

### 3 HBV transmission prevention

- 3.1 A high level of compliance with serological testing and reporting for patients is mandatory (see revised testing path schedule at Appendix 1).
- 3.2 All dialysis patients should be tested yearly for HBVsAg.
- 3.3 If a patient is found to be HBVsAg positive, the patient will need viral load studies HBV DNA (at least six-monthly).
- 3.4 Yearly screening testing for HBVcAb should be performed unless previously positive.
- 3.5 If a patient has a previously confirmed HBVcAb-positive result then no further testing of HBVcAb is needed. These patients have been infected and are at risk of reactivating the virus if they are, or become, immunosuppressed.
- 3.6 All dialysis patients should be tested yearly for evidence of HBV immunity with HBVsAb titre.
- 3.7 Patients should undergo three-monthly liver function testing to detect any hepatic illness.
- 3.8 If a potential exposure or a reactivation event has occurred, such testing may need to be more frequent.
- 3.9 A viral status (within one year) should be determined on all patients prior to starting dialysis but definitely within seven days of starting dialysis.
- 3.10 The results of a patient's viral status including HBVcAb, HBVsAg, HBVsAb, HCVAb, HIV Ab (and HBV DNA if applicable) should be available locally.
- 3.11 Patients who are positive for HBcAb, HBVsAg or HBV DNA should have HBV DNA viral load testing at least six-monthly.
- 3.12 A rising HBVsAg titre or HBV DNA copy number should prompt a review of the patient by an infectious disease physician or hepatologist.

## 4 Patient vaccination

- 4.1 All patients with CKD 4 or 5 and those on dialysis who have no serological evidence of a previous HBV infection or immunity should be encouraged to undergo a full vaccination course.
- 4.2 Patients should be vaccinated at the earliest opportunity and levels of protective antibodies assessed after a vaccination course.
- 4.3 Vaccination for CKD 4 and 5 patients consists of 40 mcg of hep B vaccination (H-B-Vax II dialysis formulation) at zero, one and six months (14).
- 4.4 Patients recently vaccinated for HBV may have false positive HBsAg, and this test should not be performed for at least three months after vaccination (14).
- 4.5 Patients who fail to develop adequate HBVsAb after the first course should be offered a second vaccination course at the same intervals (14).
- 4.6 If patients fail to seroconvert after two full courses of vaccine (six injections) then this should be noted in the patient history, but it is not necessary to offer further vaccination. However, consider subcutaneous or other vaccination strategies in some circumstances such as where a unit may be considering listing a patient for a kidney transplant and would consider a HBVcAb-positive kidney (15).
- 4.7 Dialysis patients and any patient on the transplant waiting list should be given a booster vaccination if HBVsAb titres drop below 10 IU/mL (14).

## 5 Post-exposure prophylaxis (PEP)

- 5.1 Exposure is contact of patient secretions or blood with mucous membranes, non-intact skin or via percutaneous means (for example, needlestick).
- 5.2 PEP is not required for patients or staff with detectable immunity after an exposure.
- 5.3 Non-vaccine responders (HBsAb < 10) should receive two doses of hepatitis B immunoglobulin – the first within 72 hours of an exposure (12).

## 6 Machines and environment

- 6.1 Patients who are positive for HBVsAg or HBV DNA or patients where the viral status is unknown should use a dialysis machine that is dedicated for their use only, until such time as the viral status is known or they are known to be negative.
- 6.2 Where facilities exist, haemodialysis patients with detectable HBV DNA should be treated in an isolation bay, provided that isolation is not considered detrimental to the patient's wellbeing.
- 6.3 All haemodialysis patients with detectable HBV DNA should be allocated a dedicated machine and associated equipment (such as a blood pressure cuff) solely for their own use while HBV DNA remains detectable. These machines and equipment should not be used for other patients at other times until the patient no longer has detectable circulating HBV DNA. These machines and equipment should undergo a major decontamination protocol clean before being put back into the general pool.

- 6.4 If dialysing an HBV DNA-positive patient in a non-isolated area (because isolation facilities do not exist), patients dialysing in adjacent dialysis chairs should have detectable HBVsAb > 10 (and ideally > 100 IU/mL) when last tested.

# Appendix: Pathology schedule

Test	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Na, K, HCO <sub>3</sub> , Urea, Creat												
Full blood count												
Ca,PO <sub>4</sub> ,ALP, Albumin												
Ferritin, transferrin satn												
CRP												
Tissue typing (transplant list)												
PTH												
URR and/or Kt/V												
Bili, AST,ALT, GGT												
HbA1c (Dibetics)												
B12, folate												
Magnesium												
HBVsAg, HBVsAb												
HBVcAb							Yearly unless+					
HBV DNA	ONLY if sAg or DNA+						ONLY if sAg or DNA+					
HCV,HIV												

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