Purpose
To establish minimum practice standards for Hepatitis B Vaccination in eligible patients with advanced Chronic Kidney Disease (CKD), Stage 4 and 5 CKD (defined as eGFR<30 mL/min/1.73m²) suitable for long term renal replacement therapy (dialysis and transplantation) throughout South Metropolitan Health Service (SMHS) and Western Australian Country Health Service (WACHS). This CPS has been compiled in conjunction with the Renal Health Network, however may be used in conjunction with specific site departmental requirements.

Hepatitis B vaccination is recommended for:
- All susceptible chronic haemodialysis patients
- Patients with pre-end stage renal disease before they become dialysis dependant
- Peritoneal and haemodialysis patients
- Patients vaccinated early during the course of CKD before the initiation of dialysis show higher sero-protection rates and antibody titres

Further information relating to specialty areas including Child and Adolescent Health Service (CAHS), Women and Newborn Health Services (WNHS) and Mental Health Services can be found via healthpoint.hdwa.health.wa.gov.au.

Scope
The clinical practice standard applies to all medical, nursing, midwifery and allied health staff employed within SMHS and WACHS involved in the care and management of patients with CKD. All health care professionals are to work within their scope of practice appropriate to their level of training and responsibility. Further information can be found at healthpoint.hdwa.health.wa.gov.au.

This Clinical Practice Standard also provides a scope of practice for the eligible nurses, including Renal Nurse Practitioner (RNP) for implementing Hepatitis B screening and vaccination in patients with advanced CKD.

Procedural Information
Refer to the Caring for Australasians with Renal Impairment (CARI) guidelines
Website: www.cari.org.au

Refer to Kidney Health Australia
Website: www.kidney.org.au

Refer to Centre for Disease Control and Prevention
Website: www.cdc.gov

Refer to the Renal Health Network (RHN) Website:
Where care requires specific procedures that may vary in practice across SMHS sites, staff should seek senior clinician advice.

Clinical information within this document refer to:

**Staffing requirements**
**Equipment required**
**General Information – Hepatitis B vaccination in CKD**
**Patient selection**
**Patient Assessment and Screening**
**Hepatitis B Vaccination in patients with Advanced CKD**
**Recommended Vaccination Schedule for patients with Advanced CKD**
**Potential Problems during or post procedure**
**Management after discharge**

Staff are required to consider the following requirements and comply with the relevant Operational Directives (OD)/ Information Circular (IC) and SMHS Policies located at: [www.health.wa.gov.au](http://www.health.wa.gov.au)

DoH: The National Recommendations for User-Applies Labelling of Injectable Medicines, Fluids and Lines (OD 0385/12)
DoH: The mandatory requirements outlined in Healthcare-Associated Infection Surveillance in Western Australia (OD 0197/09) and Healthcare Associated Infection Surveillance in Western Australia (IC 0042/09)
SMHS: Infection prevention strategies for all vascular access device interventions as per SMHS Infection Prevention and Management Policy (SMHS PS: 06)
SMHS: Providing care that responds to the significance of latex sensitivity/allergy in relation to the SMHS Latex Minimisation Policy (SMAHS RMQI: 05)

**Staffing Requirements**

- Staff are required to maintain the minimum level of competency that is required for their role
- Staff are required to function in relation to the SMHS Mandatory Training Policy
- Staffing levels to be undertaken safely and are appropriate for the clinical condition of the patient

**Equipment Required**

- Equipment must be appropriate for the age and/or size of the patient
- Equipment must be serviced and calibrated in accordance with manufacturer’s recommendations to ensure reliability and accuracy
- Specific sites may have pre prepared equipment packs and contents may vary
General Information – Hepatitis B vaccination in CKD

- Hepatitis B vaccination is recommended for all patients receiving dialysis as a standard of care for protection against Hepatitis associated with invasive procedures such as dialysis.
- Hepatitis B infection in patients receiving dialysis has a chronic course, associated with lesser spontaneous clearance, tendency towards chronic liver disease and increased infectivity.
- Standard precautions are mandatory during dialysis for protection from cross contamination of various blood borne viral transmissions.4,5
- Compared with immunocompetent adults, patients receiving haemodialysis are less likely to have protective levels of antibody after vaccination with standard vaccine dosages; protective levels of antibody developed in 67 – 86% (median: 64%) of adult haemodialysis patients who receive 3-4 doses of either vaccine in various dosages and schedules.
- Higher seroprotection rates have been identified in patients with chronic renal failure, particularly those with mild or moderate renal failure, who were vaccinated before becoming dialysis dependent.
- Limited data is available regarding the duration of immune memory after Hepatitis B vaccination in dialysis patients.
- No clinically important Hepatitis B Virus (HBV) infections have been documented among immunocompromised patients who maintain protective levels of HbsAb. However among patients receiving haemodialysis who respond to the vaccine, clinically significant HBV infection has been documented in persons who have not maintained HbsAb concentrations of > 10 mIU/mL.
- To improve seroconversion rates, Advisory Committee on Immunisation Practices (ACIP) recommends early vaccination of patients with renal disease and higher vaccination doses in patients receiving haemodialysis (40µg, rather than 10-20µg). Patients on haemodialysis have a shortened duration of protection compared with healthy individuals. More than 40% of patients receiving haemodialysis who respond to HBV vaccination will have undetectable HBsAb levels 3 years after vaccination.6

Patient Selection

- Patients with advanced CKD should be screened for Hepatitis B immunity prior to consideration for vaccination.
- Patients at risk for frequent hospital intervention (such as dialysis or transplantation) should be assessed at the earliest possible opportunity for vaccination.
- Standard precautions, avoidance of blood product transfusions, low prevalence of active infection in WA and use of disposable dialysis equipment has significantly reduced the risk of acquiring Hepatitis B vaccination.6

Selection Criteria

1. Advanced progressive CKD including dialysis population (eGFR <30mL/min/1.73m²) AND eligible for future renal replacement therapy including transplantation.
2. Non-immune to Hepatitis B (HbsAb level <10mIU/Ml, anti HBc negative and HbsAg negative)

Exclusion Criteria
1. Patients for non-dialytic conservative management of CKD including patients with terminal illnesses
2. Patients who are unresponsive to 2 prior courses (or 6 or more doses) of Hepatitis B vaccination
3. Screening all patients for contraindications and precautions to Hepatitis B vaccine:
   a. Contraindication: a history of severe allergic reaction (e.g. anaphylaxis) after a previous dose of Hepatitis B vaccine or to a Hepatitis B vaccine component
   b. Precaution: moderate or severe acute illness with or without fever
4. Prior severe hypersensitivity reactions to Hepatitis B vaccination

Patient Monitoring
- Predialysis patients are to be screened for immunity against Hepatitis B at the earliest opportunity (i.e. in CKD clinics, CKD education seminar, Dialysis education session/seminar and others)
- Haemodialysis and Peritoneal dialysis patients are screened on a yearly basis against blood borne diseases (HbsAb, HbsAg, Hepatitis C antibody, HIV antibody, Varicella)
- Patients with HbsAg positivity should be referred to the treating renal physician for further management

Individualised management plan to be documented in the patients’ health records as soon as is practicable. At a minimum the plan must consider:
- Patient history and diagnosis for clinical conditions, medications, psychosocial and cultural factors that could influence observations
- Presence of comorbidities and treatment
- Frequency and specific observations
- Site requirements, patient education and consent
- Any restriction to intervention associated with advance health directives (AHD) or similar

Refer to WA DoH Adult Deterioration Policy
Documentation

Failure to accurately and legibly record, and understand what is recorded, in patient health records contribute to a decrease in the quality and safety of patient care.

Refer to SMHS Documentation CPS via healthpoint.hdwa.health.wa.gov.au

Document all findings in the site specific forms and patient medical notes:
- Clinical assessment of patient
- Investigations and interventions
- Responses to interventions
- Actions initiated for medical review of patient
- Pharmacological management
- Pain treatment outcomes
- Information on patient education provided

Procedural Guideline

Key points prior to commencing any procedure
- Consider cultural, ethical and communication requirements
- Explain the procedure/s to the patient, family and/or carer and gain appropriate consent
- Patients are consulted and informed of the risks of dialysis related treatment in a hospital setting and how a collaborative approach will assist with preventing complications
- Patients should be given verbal/ written education on the prevention or management of CKD and associated signs and symptoms
- Patients are informed of the possible side effects of medications prescribed, including anticoagulant therapy
- Review patient history and diagnosis for clinical conditions, medications and psychosocial factors that could influence observations
- Refer to previous observation parameters if available for comparison

Patient Assessment and Screening

Patients for vaccination are screened for Hepatitis B surface antigen (HBsAg) and Hepatitis B surface antibody (HBsAb)
- HbsAb positivity suggests prior active infection rather than immunity due to inadvertent prior vaccinations
- HBV RNA should be considered with positive HbsAg and active liver disease
- All patients with advanced CKD should be consented and tested before they commence dialysis as part of a routine initiation screening procedure for:
  - Hepatitis B surface antigen (HBsAg)
  - Hepatitis B surface antibody (HBsAb)
  - Hepatitis C antibody (HCV)
  - Hepatitis C RNA (if indicated)
- Human Immunodeficiency virus (HIV) antibody
- Varicella antibody

Informed verbal consent is required for all blood borne viral testing

Refer to local site policies and procedures regarding Blood Sampling for the Dialysis Patient - Phlebotomy and Cannulation procedures

- Patients receiving Haemodialysis and Peritoneal Dialysis are to be screened via blood testing annually
- Standard precautions are to be used at all times to minimise the transfer of blood borne pathogens
- Results of screening test will be reviewed by a Medical Officer (MO)/eligible Renal Nurse Practitioner and documented in patient health record

Refer to site policies and and guidelines for Medication Administration. See Medications CPS, via healthpoint.hdwa.health.wa.gov.au.

### Recommended Vaccination Course Schedule

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dose</th>
<th>Vaccination Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energix B™</td>
<td>40 µg</td>
<td>0, 1, 2 and 6 months</td>
</tr>
<tr>
<td></td>
<td>2mL*</td>
<td></td>
</tr>
<tr>
<td>H-B_Vax II™ (Dialysis Formulation)</td>
<td>40 µg</td>
<td>0, 1 and 6 months</td>
</tr>
<tr>
<td></td>
<td>1mL</td>
<td></td>
</tr>
</tbody>
</table>

*1.0 mL of Engerix-B adult formulation (20 µg) is administered into each arm as per Vaccination Frequency schedule

- Booster doses of Hepatitis B vaccine are recommended for patients who still have HBsAb levels below 10mIU/ml after completion of the primary three doses of Hepatitis B vaccine
- A maximum of 3 consecutive annual booster doses will be given after which annual screening of BBV is continued
- Final serology is checked at the 7th month and reviewed by Medical Officer
Table 1: Vaccination schedule

<table>
<thead>
<tr>
<th>Administration Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Administer Hepatitis B vaccine intramuscularly (22-25g, 1-1½” needle) into the deltoid muscle.</td>
</tr>
<tr>
<td>2. The anterolateral thigh muscle may be used if deltoid is inadequate.</td>
</tr>
</tbody>
</table>

Note: 5/8” needle may be used for adults weighing less than 130lbs (60kg) for injection into the deltoid muscle only if the subcutaneous tissue is not bunched and the injection is made at a 90-degree angle

3. Be prepared for management of a medical emergency related to the administration of the vaccine by having a written emergency medical protocol available, as well as equipment and medications.
4. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing patient for 15 minutes after receipt of the vaccine.

5. Report all adverse reactions to Hepatitis B vaccine to the Federal Vaccine Adverse Event Reporting System as per site policy.

6. Document each patient’s vaccine administration information and follow up in the patient's health record:
   a. **Medication chart**: Record the date the vaccine was administered, the manufacturer and lot number, vaccination site and route, name and title of the person administering the vaccine. If the vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g. medical contraindication, patient refusal).
   b. **Statewide e-database**
   c. **Personal immunization record card**: record the date of the vaccination and the name/location of the administering clinic.

### Potential Problems During or Post Procedure

- Patients not seroconverted post vaccination may require:
  - Booster dose – to be prescribed by Medical Officer
  - Referral to Immunology department if they require Intradermal Hepatitis B vaccination

### Management after discharge

Refer to site policies and guidelines regarding discharge processes, patient education and follow up for postoperative patients.

### Clinical Handover

Information exchange should adhere to the WA Health Clinical Handover Policy (iSoBAR).
Compliance Monitoring

Evaluation, audit and feedback processes should be in place to monitor compliance.
Acknowledgement of previous site endorsed work used to compile this standard

We would like to thank the following people for their contribution to the project:

Armadale Health Service, Renal Nurse Practitioner Clinical Practice Guideline – Hepatitis B Vaccination in Late (Stage 4 and 5) Chronic Kidney Disease, December 2009
  Kulkarni, H Dr – Renal Physician, Armadale Health Service (AHS)
  Light, C - Renal Nurse Practitioner, AHS

Fremantle Hospital and Health Service, Blood Borne Virus Screening and Immunisation for Renal Patients Protocol, July 2009
  Porter, S – CNS Renal Unit, FHHS

The Renal Health Network

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Virahsawmy, S – Senior Dietitian, AHS
Vukovich, I – Principal Social Worker, AHS
**Legislation**

Acts Amendment (Consent to Medical Treatment) Act 2008  
Carers Recognition Act 2004  
Civil Liability Act 2002  
Disability Services Act 1993  
Guardianship and Administration Act 1990  
Health Practitioner Regulation National Law (WA) Act 2010  
Mental Health Act 1996  
Occupational Safety and Health (OSH) Act, 1984 (Amended 2011)  
OSH Regulations, 1996  
Poisons Act 1964  
Poisons Regulations 1965  
Poisons Amendment Regulations 2010  
Public Sector Management Act, 1994  
State Records Act 2000 - The children and community Services Amendment (Reporting Sexual Abuse of Children) Act 2008  
The Children and Community Services Amendment Bill 2010

**Standards**

National Standards for Mental Health Services (NSHMS)

**WA Department of Health Policies (Operational Directives)**

[healthpoint.hdwa.health.wa.gov.au](http://healthpoint.hdwa.health.wa.gov.au)  
Clinical and Related Waste Management – Clinical Wastes (OD 0259/09)  
Clinical Handover Policy, 2012 (OD 0403/12)  
Clinical Incident Management Policy, 2012 (OD 0421/13)  
Consent to Treatment Policy for the Western Australian health system, 2011 (OD 0324/11)  
Correct Patient, Correct Site and Correct Procedure Policy and Guideline for WA Health Services 2nd Edition (OD 0004/06)  
Implementation of the Australian Health Service Safety and Quality Accreditation Scheme and the National Safety and Quality Health Service Standards in Western Australia (OD 0410/12)  
Medical Emergency Response (OD 0040/07)  
National Hand Hygiene Initiative in Western Australian Healthcare Facilities (OD 0429/13)
The Policy for Credentialling and Scope of Clinical Practice for Medical Practitioners 2nd Edition 2009 (OD 0177/09)
Western Australian Patient Identification Policy 2010 (OD 0312/10)
Post-Fall Management Guidelines in Western Australian Healthcare Settings (OD 0442/13)

SMHS Policies

healthpoint.hdwa.health.wa.gov.au
Aboriginal and Multicultural Groups (SMAHS CF: 02)
Bariatric Management: (SMAHS COC: 06)
Consumer and Carer Participation: (SMAHS CF: 03)
Consumer and Carer Participation in Mental Health: (SMHS CF: 07)
Health Record Documentation Policy and Standards (SMAHS COC: 03)
Infection Prevention and Management Policy (SMHS PS:06)
Mandatory Training Governance Policy (SMHS HR: 04)
OSH: Manual Handling (SMAHS SPE: 04)
Single Use/Single Patient Use Medical Devices: (SMAHS SPE: 40)
**Title:** Renal: Hepatitis B Vaccination - Patients with Advanced Chronic Kidney Disease (CKD) Clinical Practice Standard

**SMHS Code:** CPSR003

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**Standardised Logos**

EQuIPNational [www.achs.org.au](http://www.achs.org.au/8,9)

<table>
<thead>
<tr>
<th>Governance for Safety and Quality in Health Service Organisations</th>
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<tbody>
<tr>
<td>Partnering with Consumers</td>
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<tr>
<td>Preventing and Controlling Healthcare Associated Infections</td>
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<tr>
<td>Medication Safety</td>
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<tr>
<td>Patient Identification and Procedure Matching</td>
</tr>
<tr>
<td>Clinical Handover</td>
</tr>
</tbody>
</table>

**WA Department of Health iSoBAR - Guide to Handover Content and Structure**

<table>
<thead>
<tr>
<th>i</th>
<th>IDENTIFY</th>
<th>Introduce yourself and your patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>SITUATION</td>
<td>Describe the reason for handing over</td>
</tr>
<tr>
<td>o</td>
<td>OBSERVATIONS</td>
<td>Include vital signs and assessments</td>
</tr>
<tr>
<td>B</td>
<td>BACKGROUND</td>
<td>Pertinent patient information</td>
</tr>
<tr>
<td>A</td>
<td>AGREE A PLAN</td>
<td>Given the situation, what needs to happen</td>
</tr>
<tr>
<td>R</td>
<td>READ BACK</td>
<td>Clarify shared understanding</td>
</tr>
</tbody>
</table>

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**Blood and Blood Products**

**Preventing and Managing Pressure Injuries**

**Recognising and Responding to Clinical Deterioration in Health Care**

**Preventing Falls and Harm from Falls**

**Service Delivery**

**Provision of Care**

**Workforce Planning and Management**

**Information Management**

**Corporate Systems and Safety**

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Approved Renal Health Network:
References


