Hepatitis B Vaccination in Chronic Kidney Disease UHL Renal Guideline

University Hospitals of Leicester NHS
NHS Trust

CMG RRCV

Trust Ref: C6/2016

1. Introduction and Who Guideline applies to

Historically, hepatitis B has caused problems in patients with renal failure treated by haemodialysis. In the 1970's, several outbreaks led to significant morbidity and mortality amongst patients and staff in renal units in the UK. The identification of the Hepatitis B virus, careful and regular screening of patients with renal failure for Hepatitis BsAg (HBsAg) and application of universal precautions have prevented recent problems. However, the Department of Health(1) and the Renal Association(2) recommend immunisation of all patients with chronic renal failure who require (or are likely to require) renal replacement therapy. Patients on dialysis are immunosuppressed and do not respond well to immunisation. Studies have suggested that 45-85% of patients will develop measurable anti-HBs antibody (anti-HBs) with the higher percentage achieved where larger vaccine doses are used(1). Therefore it is prudent to immunise patients who are likely to require dialysis at an earlier stage and use an increased dose.

This guideline is to advise qualified staff caring for patients with Chronic Kidney Disease on or preparing for dialysis to vaccinate patients against Hepatitis B.
Clinical guidelines are 'guidelines' only. The interpretation and application of clinical guidelines will

2. Guideline Standards and Procedures

2.1 Patients who should be vaccinated

- Patients who are pre-dialysis as soon as it is clear that they are likely to need renal replacement therapy and ideally when estimated glomerular filtration rate is >30ml/min. Seroconversion is improved at higher GFR.

- All new or prevalent patients with established renal failure(ERF) treated by dialysis or transplantation who have not been previously vaccinated or have anti-HBs<10

3.1.2 Hepatitis B vaccine is not indicated in patients who have current (Hepatitis B surface antigen (HBsAg) positive or HBV DNA positive) or confirmed past HBV infection. Presence of the anti HBc antibody in isolation should not be taken as confirmation of previous HBV infection and the case should be discussed with a local virologist.

2.2 Vaccination Schedule

There are three licensed products available in the UK. Patients with renal failure require higher than standard doses of vaccine in order to mount an adequate response. The three regimes suggested by the BNF are:-

Vaccine type	Dose	Formulation	Schedule (months)
Engerix B®	40micrograms	2 x 20 microgram iml injections	0,1,2 and 6
HBvaxPRO®	40micrograms	2 x 40 microgram 1 ml injection	0, 1 and 6
Fendrix®:	20micrograms	1 x 20 mincrogram 0.5 ml injection	0,1,2 and 6

Availability of product is likely to vary.
NB Deltoid muscle is preferred site of injection in adults and older children; subcutaneous route used for patients with thrombocytopenia or bleeding disorders
A standard letter(see appendix 1) should be sent to general practitioner.

2.3 Follow up and monitoring

2.3.1 Check antibody levels 8 weeks after final dose in the vaccination schedule

- Patients should be regarded as an 'adequate responder' if the anti HBs antibody titre is >100mIU/ml 8 weeks after completing the immunisation schedule.
- Responders to HBV immunisation should receive a further booster dose if the annual anti HBs titre is <100mIU/ml.
- Patients should be regarded as an inadequate-responder if the anti HBs antibody titre is <100mIU/ml 8 weeks after completing the first complete immunisation schedule.
    - If the anti HBs Ab titre is between 10IU/ml and 100IU/ml administer a booster dose of the vaccine.
    - If the anti HBs titre is <10IU/ml repeat the entire vaccination course. Follow up with an anti-HBs antibody titre test 4 to 6 weeks following the last injection to ensure it is greater than 10m IU/l.
    - If after two full vaccination courses the Anti HBs titre remains <10mIU/ml the patient should be considered as a non-responder to the vaccine, and therefore not immune to HBV.
    - A non-responder patient, who is therefore not immune to HBV, should be counselled about how to minimize risk of HBV exposure and the recommended actions needed to take in the advent of a potential Hepatitis B exposure (this is likely to include urgent receipt of Hepatitis B immunoglobulin). (RA, 2019)

2.3.2 Annual follow-up

- All established renal failure and pre-dialysis patients should have anti HBs level checked annually UNLESS THEY HAVE PREVIOUSLY BEEN SHOWN TO BE NON-RESPONDERS OR ARE HEPATITIS BsAg POSITIVE. For simplicity following in years following the steps in 3.3.1 a concentration of >10mIU/ml is considered to be adequate. Patients whose concentrations were >10IU/ml but subsequently falls below this concentration should be given booster doses. If anti-HBs remains < 10 IU/ml they should be reclassified as 'non-responder' (see above)

2.3.3 Non-responders

- The following groups of patients will be classified as 'non-responders' and should simply have regular check of HBsAg
- patients who do not respond to two full courses of Hep B vaccine in double dose
- patients who initially respond then drop anti-HBs concentration to <10 IU/ml which does not increase after a booster dose

2.4 Special situations

- Patients training for home haemodialysis should have their antibodies checked and acted on as above during their training period.
- Home haemodialysis assistants actively participating in dialysis should be offered vaccination
- Responders to the HBV vaccine should have the anti HBs titre checked prior to travel overseas, with a booster dose administered if the Anti HBs antibody titre is<100miU/ml.
- Responders to the HBV vaccine should have the anti HBs titre checked following high risk exposure, with a booster dose administered if the Anti HBs antibody titre is<100miU/ml.

2.5 Secondary Care

- Hepatitis B vaccination was previously administered in primary care but responsibility of giving this vaccination to renal patients is now given to to secondary care providers.
- The vaccine type provided by UHL pharmacy is subject to product availability.

- Nursing staff administering the vaccine need to be vaccination trained and transined in the use of PGDs
- The Hepaitis B vaccination PGD should be used
- Staff administering the vaccine need to complete a vaccine record and complete a blueteq form.

3. Education and Training

Medical staff from nephrology and transplant service and nursing staff (ward nurses, haemodialysis nurses and renal community team) should be familiar with guideline and access it for specific advice on dosing..

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Prevalence of Hep B immunity in HD population	Audit using UKRR enquiry	James Medcalf	Quarterly	

5. Supporting References (maximum of 3)

1. Good practice guidelines for renal dialysis and transplantation units. Prevention and control of blood borne virus infection. Department of Health, London, Sept 2002
2. Renal Association (2019) Recommended infection control practices for haemodialysis units. Accessed online https://renal.org/sites/renal.org/files/FINAL-BBV-Guideline-June-2019.pdf [30.10.20]
3. PHE (2019) Hepatitis B vaccine for renal patients: patient group direction template. online https://www.gov.uk/government/publications/hepatitis-b-vaccine-for-renal-patients-patient-group-direction-template [Accessed 30.10.20]

Clinical Practice Guideline: Management of Blood Borne Viruses within the Haemodialysis Unit

6. Key Words

blood borne virus, hepatitis B, vaccination, chronic renal failure, dialysis

CONTACT AND REVIEW DETAILS	
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Details of Changes made during review: Reference to new RA guidelines. Insertion of dosing table.	