Vaccination Policy for Patients with Chronic Kidney Disease (CKD) Hepatitis B

Your patient with renal impairment needs to be vaccinated against Hepatitis B in accordance with Public Health England: ‘Hepatitis B: guidance, data, analysis and Immunisation against infectious disease- The green book Chapter 18- July 2017.’

Hepatitis B Vaccination
Hepatitis B vaccination should be offered to
1) All patients on Renal Replacement Therapy (RRT) (haemodialysis, peritoneal dialysis and renal transplant).
2) CKD stage 4 or 5 (Unless it is felt unlikely that they will ever need RRT).
3) CKD stage 3 only if advised by a renal consultant.

Based on the current supply constraints please see the choice of vaccinations and order of preference below:

Table 1: Choice of vaccinations and order of preference:

<table>
<thead>
<tr>
<th>Order of preference</th>
<th>Adults of any age with renal failure who are pre-dialysis or on dialysis / renal transplantation programmes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt;</td>
<td>High Ag content HepB vaccine; Fendrix: 20 micrograms I.M given at 0,1,2 and 6 months OR HBVaxPRO40: 40 micrograms I.M given at 0,1 and 6 months</td>
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<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt;</td>
<td>Adult monovalent HepB vaccine EngerixB: 40 micrograms I.M (2 x 20mcg) given at 0,1,2 and 12 months OR HBVaxPRO: 40 micrograms I.M given at 0,1 and 6 months</td>
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<tr>
<td>3&lt;sup&gt;rd&lt;/sup&gt;</td>
<td>High dose adult combination HepA / HepB vaccine Twinrix: 20micrograms I.M. given at 0,1 and 6 months</td>
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<tr>
<td>4&lt;sup&gt;th&lt;/sup&gt;</td>
<td>Two simultaneous doses of paediatric combination HepA/HepB vaccine Twinrix paediatric: 20micrograms (2 x 10mcg) I.M. given at 0, 1 and 6 months.</td>
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Where possible, the same vaccine should be used for any given course including subsequent annual boosters as required. However if supplies of any given vaccine become unavailable part way through an immunisation course or a booster dose is needed, it is reasonable to complete the course or administer a booster dose with an alternative vaccine (see appendix 1 for compatibility information when switching brand).

Monitoring

In immunocompromised subjects (e.g. subjects with chronic renal failure, haemodialysis patients and HIV positive subjects), boosters should be administered to maintain anti-HBs antibody concentrations equal or higher than the accepted protective level of 10 IU/L. For these immunocompromised patients, post-vaccination testing every 12 months is advised.

Please see the figure below for monitoring information: (Note: 1 mIU/ml=1 IU/L).
Figure 1: Antibody Level Monitoring

**Completion of vaccination programme**

Check antibody levels approximately 1-2 months after completion.

**Antibody levels >100 IU/L** → booster not required but antibody levels checked annually.

**Antibody levels 10-100 IU/L** → should receive one additional booster dose of vaccination. Continue to check antibody levels annually.

**Antibody levels <10 IU/L** → Classified as non-responders and testing for markers of current or past infection is good clinical practice. A repeat second full course of vaccination is recommended, followed by re-testing for antibodies one to two months after the second course. Those who still have anti-HBs levels <10 IU/L, with no markers of current or past infection, will require Hepatitis B Immunoglobulin for protection if exposed to the virus (if required please discuss with microbiology prior to contacting pharmacy). **Otherwise no further courses of vaccination to be offered to this group.**

**Annual Antibody Level**

- **anti-HBs < 10IU/L**
  - Administer a booster dose of HepB vaccine. Perform post-vaccination serologic testing 1-2 months after booster dose.
  - anti-HBs < 10IU/L

- **anti-HBs ≥ 10IU/L**
  - Complete a vaccination programme treating the previous booster dose as dose 1. Perform post-vaccination serologic testing 1-2 months after last dose of vaccine.

- **anti-HBs < 10IU/L**

If patient has received ≥6 doses of HepB vaccine and have anti-HBs <10IU/L. They are considered to be a non-responder. Patient should receive hepatitis B evaluation for all exposures.

Reviewed by Imran Anwar

Next review: September 2019
Booster doses should also be offered to any haemodialysis patients who are intending to visit countries with a high endemicity of hepatitis B and who have previously responded to the vaccine, particularly if they are to receive haemodialysis and have not received a booster in the last 12 months.

**Precautions**

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.

- **Pregnancy and breast-feeding**

  Hepatitis B infection in pregnant women may result in severe disease for the mother and chronic infection of the new born. Immunisation should not be withheld from a pregnant woman if she is in a high-risk category. There is no evidence of risk from vaccinating pregnant women or those who are breastfeeding with inactivated viral or bacterial vaccines or toxoids. Hepatitis B is an inactivated vaccine, risks to the foetus are likely to be negligible. It should be given if there is a definite risk of infection.

- **HIV and immunosuppressed individuals**

  Hepatitis B vaccine may be given to HIV-infected individuals and should be offered to those at risk, since infection acquired by immunosuppressed, HIV positive patients can result in higher rates of chronic infection. Response rates are usually lower depending upon the degree of immunosuppression. Increasing the number of doses may improve the anti-HBs response in HIV-infected individuals. Further guidance is provided by the Royal College of Paediatrics and Child Health (www.rcpch.ac.uk) the British HIV Association (BHIVA) immunisation guidelines for HIV-infected adults (BHIVA, 2006) and the Children’s HIV Association of UK and Ireland (CHIVA) immunisation guidelines (www.chiva.org.uk).

**Pneumococcal Vaccination**

- Haemodialysis, peritoneal dialysis, renal transplant, CKD stage 3 to 5, nephrotic syndrome and immunosuppressed patients should be offered a single dose of Pneumococcal Polysaccharide Vaccine (PPV), followed by a booster dose of PPV every five years. Routine testing of antibody levels is not required prior to vaccination or re-vaccination. PPV can be given in any season.

**Influenza Vaccination**

- Haemodialysis, peritoneal dialysis, renal transplant, CKD stage 3 to 5, Nephrotic syndrome and immunosuppressed patients should be offered vaccination against seasonal flu between October and November annually to ensure they are protected during the winter months.
## Appendix 1

Compatibility Table: Using Different Vaccination Preparations to either complete an Immunisation Programme or offer a Booster Dose.

<table>
<thead>
<tr>
<th>Brand</th>
<th>Primary immunisation</th>
<th>Booster dose</th>
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<tbody>
<tr>
<td><strong>Fendrix®</strong></td>
<td>NOT interchangeable with any other commercially available HBV vaccine.</td>
<td>Fendrix can be used as a booster dose after a primary vaccination course with either Fendrix or any other commercial recombinant hepatitis B vaccine.</td>
</tr>
<tr>
<td><strong>HBVaxPRO40®</strong></td>
<td>Can be used to complete a primary immunisation course in subjects who have previously received another hepatitis B vaccine.</td>
<td>Can be used as a booster dose in subjects who have previously received another hepatitis B vaccine.</td>
</tr>
<tr>
<td><strong>Engerix B®</strong></td>
<td>Engerix B may be used to complete a primary immunisation course started either with plasma-derived or with other genetically-engineered hepatitis B vaccines.</td>
<td>Engerix B may be used to administer a booster dose to subjects who have previously received a primary immunisation course with plasma-derived or with other genetically-engineered hepatitis B vaccines.</td>
</tr>
<tr>
<td><strong>Twinrix® Adult</strong></td>
<td>NOT interchangeable with any other commercially available HBV vaccine.</td>
<td>In situations where a booster dose of both hepatitis A and hepatitis B are desired, Twinrix Adult can be given. Alternatively, subjects primed with Twinrix Adult may be administered a booster dose of either of the monovalent vaccines.</td>
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<tr>
<td>Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed).</td>
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<tr>
<td><strong>Twinrix® Paediatric</strong>, suspension for injection hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed).</td>
<td>NOT interchangeable with any other commercially available HBV vaccine.</td>
<td>In situations where a booster dose of hepatitis A and/or hepatitis B is desired, a monovalent or combined vaccine can be given. (The safety and immunogenicity of Twinrix Paediatric administered as a booster dose following a three dose primary course have not been evaluated).</td>
</tr>
<tr>
<td>Two simultaneous doses of paediatric combination HepA/HepB vaccine (Twinrix paediatric)</td>
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