Norfolk and Norwich Simple Hepatitis B Vaccination and Surveillance Guide

(Don't immunise patients if HBsAg +ve)

CONTENT

1.Context

Patients on a chronic haemodialysis programme may be at higher risk of acquiring the hepatitis B virus. Therefore, it is recommended that patients who require renal replacement therapy for chronic kidney disease should be immunised against the hepatitis B virus. Patients with renal failure have a lower response rate than healthy adults. Only 45-66% of chronic renal failure patients develop a hepatitis B surface antibody (anti-HBs) response, and levels of anti-HBs decline more rapidly than in immunocompetent individuals. (ref 1-3)

Higher (double) doses of vaccine have been shown to be more effective, and most studies have shown a 4 dose regimen to be more effective and logistically easier than identifying non-responders requiring a "booster dose" (ref 5). **This is the key point in our vaccination schedule**.

The most successful strategy is to vaccinate those likely to require renal replacement therapy, whenever possible, early in the course of their renal disease but certainly when eGFR <30mls/min.(ref 2,3).

There is no good evidence to support the value of booster vaccination in the dialysis population, the frequency of re-testing or the rate of decline in immunity for those patients who have made a full or partial response to the original vaccination schedule.

2. Purpose and scope

To ensure that all renal patients are appropriately immunised against the hepatitis B virus in a safe and timely manner. To improve the uptake and effectiveness of hepatitis B immunisation.

3. Patient selection criteria

All patients with chronic renal failure attending a low clearance clinic or nephrology clinic with a likely prospect of starting renal replacement therapy (RRT) and a eGFR of <35mls/min and those in the "chronic dialysis" programmes.

4. Exclusion criteria

- Acute renal failure patients

• Patients under 15 years of age.

• Patients with a significant allergy to a previous Hepatitis B vaccine

• Patients with a known hypersensitivity to any of the vaccine excipients (include dosium chloride, borax, water for injections)

• Non responders to hepatitis B vaccination

• Patients with an acute severe febrile illness (administration should be postponed)

5. Statement of protocol

Presentation: **HBvaxPRO®** is available as a 1ml suspension for injection containing 40mcg/ml hepatitis B virus surface antigen.

Dose: 40 micrograms in 1ml

Route: Intramuscular injection in the deltoid region (not fistula arm)

Frequency: 4 dose schedule. Vaccinations at 0, 1, 2 and 6 months.

HBvaxPRO® can be administered to complete a primary immunisation course or as a booster dose in patients who have previously received another hepatitis B vaccine. (ref 4)

6. Follow up: Will be undertaken by Renal Department.

Check anti-HBs antibody titres 8 weeks post immunisation.

Titre <10mIU/ml – regard as non responder.

Record 'Non responder to hepatitis B vaccine' in medical notes and on Emed. No further vaccinations recommended.

Titres 10 to 99mlU/ml record as Partial Responder – record on Emed and ensure annual HBs antibody titre measured and follow protocol below.

Titre >100mlU/ml regarded as Responder – Record on Emed with date of test result.

Responders and Partial Responders to the hepatitis B vaccination should have their antibody titre checked annually and receive a further booster dose of 40mcg if the anti-HBs antibody titre is <10mIU/ml (i.e. a significant drop in antibody titre).

Antibody titres of 10 -99IU/ml in previous responders should not receive a booster dose unless high risk behaviour or travel to endemic region.

7. References:

1. Department of Health. Immunisation against infectious disease 1996 – 'the Green Book'. Chapter 18: Hepatitis B. London: DH, 1996.
http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_108820.pdf

2. Department of Health. Good practice guidelines for renal dialysis/transplantation units: prevention and control of blood-borne virus infection. London: DH, 2002.
http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4059511.pdf

3. The Renal Association. RA Guidelines – blood borne viral infection. July 2009.
http://www.renal.org/Clinical/GuidelinesSection/BloodBorneVirusInfection.aspx

4. SPC. Sanofi Pasteur MSD. HBVAXPRO 40mcg SPC. Electronic Medicines Compendium. Last updated: 28/11/2008. http://emc.medicines.org.uk/

5. Charest AF, McDougall J, Goldstein MB. A randomised comparison of intradermal and intramuscular vaccination against hepatitis B virus in incident chronic haemodialysis patients. Am J Kidney Dis 2000, 36; 976-982.

Alternatives in event of a supply problem.

In the event of a supply problem with HBvaxPRO 40®, the alternatives are:

Engerix B® 4 doses of 40microgram (2 x 20microgram) At month 0, 1, 2 and 6.

Or

Fendrix® 4 doses of 20microgram (0.5ml prefilled syringe) At months 0, 1, 2 and 6.

Both are given by intramuscular injection preferably into the deltoid muscle.

When possible, use the same brand for the whole primary immunisation course. Note HBvaxPRO® or Fendrix® can be used to administer a booster dose in patients who have previously received a primary course with an alternative hepatitis B vaccine.

Summary for GP colleagues and Practice Nurses

a) **Letter from Renal Department asking if you would kindly help to vaccinate a pre-dialysis patient. All patients will be asked to make a very routine contact with your Practice to discuss this request.**
b) **Please note the schedule below has a "built-in booster dose" . It has four doses and is not the same as the BNF schedule.**

c) **HBvaxPRO® 40 micrograms IM into deltoid (avoid fistula arm if present)**

a. Time zero	**Date of 1st vaccination ……**
b. 1 month	**Date of 2nd vaccination ……**
c. 2 months	**Date of 3rd vaccination ……**
d. 6 months	**Date of 4th vaccination ……**

RENAL DEPARTMENT WILL CHECK Hepatitis B surface antibody at least 2 months post last vaccination and record result.

Annual surveillance of HBs antibody status will be responsibility of RENAL DEPARTMENT.

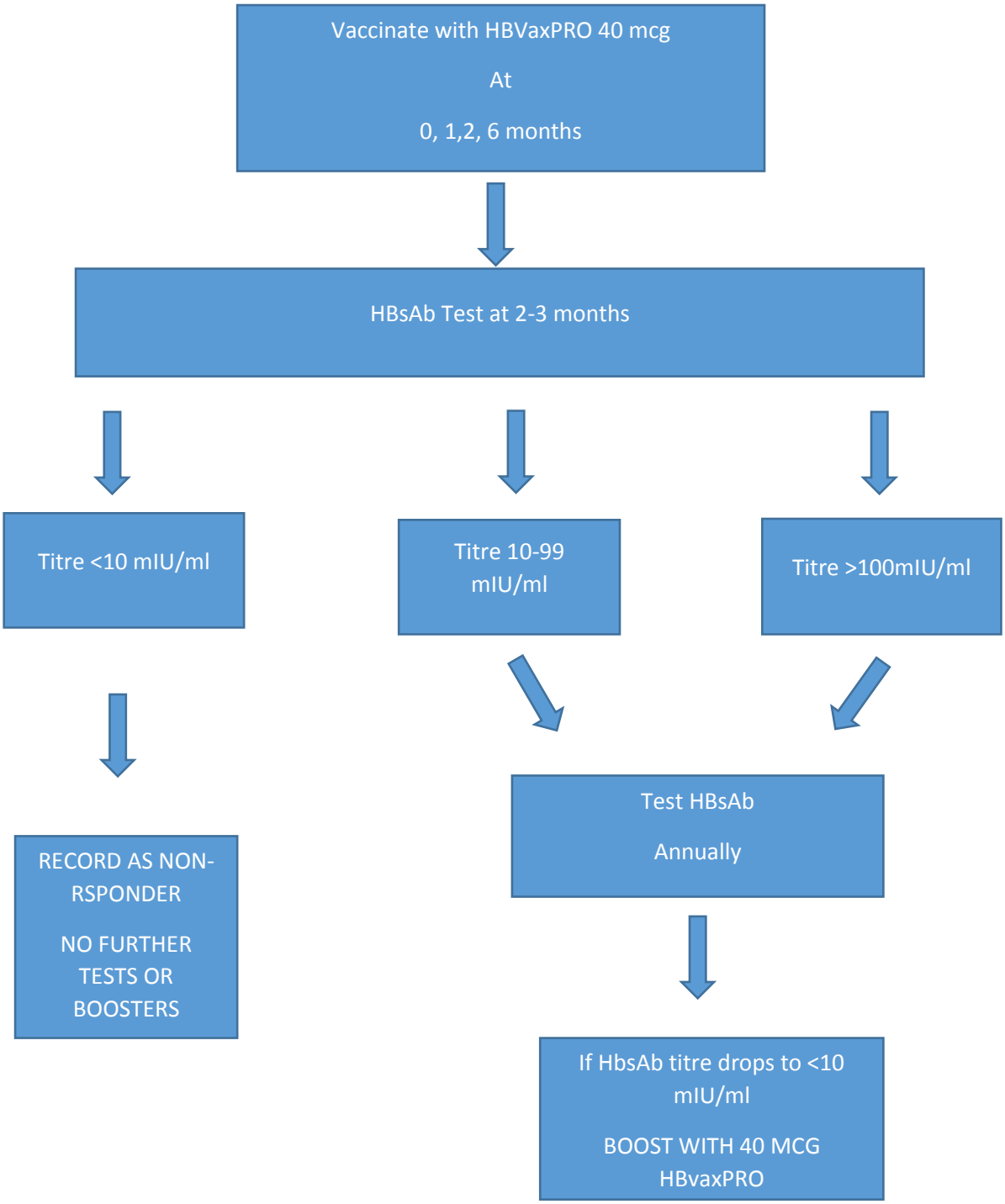
Thank you for your help with this essential preparation for dialysis. If there are problems helping with preparation of your patient, please contact the consultant responsible for your patient.

Dr Mark J Andrews FRCP

Consultant Nephrologist

Specialty Director for Renal Medicine on behalf of the Renal Department

16/11/16



If patient with previous non-response or partial response is subject to high risk incident . CONSIDER REPEATING 4 DOSE COURSE OF VACCINATION