

Guidelines for the Administration of Hepatitis B Vaccination to Renal Patients

CATEGORY:	Procedural Document
CLASSIFICATION:	Clinical
PURPOSE	These clinical guidelines provide guidance for registered nurses and medical staff working within the renal specialty, who manage the care of patients requiring Hepatitis B vaccination
Controlled Document Number:	763
Version Number:	002
Controlled Document Sponsor:	Medical Director, Division B Associate Director of Nursing, Division B
Controlled Document Lead:	Lead for Haemodialysis Lead for BBV
Approved By:	Blood Borne Virus (BBV) Steering Committee
On:	Jan 2017
Review Date:	Jan 2020
Distribution:	<ul style="list-style-type: none"> Essential Reading for: The registered nurses and medical staff who manage the care of renal patients requiring Hepatitis B vaccination. Information for: All clinical staff working in the renal specialty.

1. Scope

These guidelines apply to all registered nurses and medical staff, working within the renal speciality, who manage the care of patient requiring Hepatitis B vaccination. The renal speciality includes renal inpatient areas, outpatient areas and dialysis units whether Trust run or provided in partnership arrangements.

2. Key terms

HBsAB	Hepatitis B surface antibody. Produced by immune system as a response to previous immunisation or infection. Routinely used as measurement of immunity induced by vaccination.
HBsAG	Hepatitis B surface antigen. Present when individual currently infected and infective with Hepatitis B.
HBcAB	Hepatitis B core antibody. Produced by immune system in response to previous infection. Not an indication of protection from infection. Should still be vaccinated using HBsAB measurement. Occasionally can reactivate infection and therefore subjected to more intensive screening for HBsAG.

- 2.1 For more information on protocols for care of patients with Hepatitis B, routine screening regimes and need for isolation or cohort nursing see:

‘Clinical procedure for screening, prevention and management of blood borne virus in patients under the care of UHB renal services’:
<http://uhbpolicies/assets/BloodBorneVirusesProcedure.pdf>

‘Protocols for screening, prevention and management of blood borne virus of patients under the care of UHB renal services, 2nd edition’:
[http://uhbpolicies/assets/BloodBorneVirusScreeningRenalPatients.p
df](http://uhbpolicies/assets/BloodBorneVirusScreeningRenalPatients.pdf)

3. Introduction

- 3.1 Hepatitis B is a blood borne virus (BBV), which has historically been associated with nosocomial spread within the haemodialysis population. For this reason all patients undergoing dialysis are regularly screened for exposure and offered vaccination. This, along with strict infection control practices, should reduce risk to both patients and staff. The current Department of Health (2002) and Renal Association (2009) advice is that: “immunisation against hepatitis B is recommended for patients already on haemodialysis or renal transplantation programmes, and for other patients with chronic renal failure as soon as it is anticipated that they may require these interventions. The vaccines formulated for use in patients with chronic renal insufficiency should be used.” This document outlines the Trust’s vaccination programme for patients with advanced renal disease

and are based on these national guidelines. Publication of any new national guidance will require review and update as necessary of this document.

- 3.2 Because patients with advanced renal disease have a decreased immune response to vaccinations against Hepatitis B, vaccination should begin before the requirement for renal replacement therapy so that ample opportunity for development of immunity has been allowed. Therefore the CKD team will identify patients with an eGFR of 20ml/min/1.73m² and commence screening and vaccination if appropriate as documented within this guideline. However some patients are not known to renal services prior to commencement of dialysis and they should also be offered vaccination as soon as possible using the same regimes.
- 3.3 For patients' receiving vaccination in UHB clinics, verbal consent is obtained, the patient is given the patient information leaflet 'Hepatitis B, Hepatitis C and HIV testing for people with chronic kidney disease and those on dialysis' (<http://www.uhb.nhs.uk/Downloads/pdf/PiHepatitisHivTestingCkd.pdf>) and this is documented in the patient record and also within MARSII renal database. The vaccination is administered and recorded as per prescription (Appendix 1) and noted in MARSII renal database for auditing evidence. If a patient is mid-way through the course of vaccinations and they move dialysis units, the original prescription must go with them. The vaccination must not be administered from any photocopy of the original prescription. Appendix 2 contains the vaccination cards.
- 3.4 Within partnership dialysis organisations, the BBV link nurse will regularly review need for vaccination in the cohort of patients. Communication with satellite liaison team will allow issuing of prescriptions for vaccination. Verbal consent will be obtained and recorded within the provider's electronic record. Administration of vaccine must then be confirmed by email as per UHB requested pathways to allow MARSII renal database update.

4. Immunisation in renal patients

- 4.1 Achieving adequate protection in patients with advanced renal disease can be challenging .Titres of anti HBsAb are measured as:
- | | |
|-------------|------------------|
| >100IU/ml | good response |
| 10-100IU/ml | partial response |
| <10IU/ml | no response |
- 4.2 The aim of the vaccination programme is to induce an antibody response of at least 10 IU/ml and preferably 100 IU/ml in as many patients as possible.

5. Staff Training

5.1 Hepatitis B vaccinations must be administered by registered nurses. Staff are required to:

- be competent in obtaining informed consent from patients for BBV screening (informed consent training);
- be competent in the provision of information regarding the need to vaccinate (UHB BBV training); and
- have completed the BLS and anaphylaxis training prior to undertaking administration of vaccinations (mandatory training).

5.2 UHB staff must transferring in from elsewhere must complete UHB BBV training before administering Hepatitis B vaccinations to UHB patients.

6. Administration

6.1 These guidelines provide guidance on the administration of the following Hepatitis B vaccines only: HBVaxPro or Engerix B. HBVaxPro is the preferred option if available.

Patients, who are allergic to latex, must not receive HBVaxPro. They can receive Engerix B.

6.2 Hepatitis B injections are to be administered intramuscularly into the deltoid muscle within the last 30 minutes or after dialysis if during a dialysis session. Injection into subcutaneous fat should be avoided as will decrease efficiency of vaccination. Because of the use of anticoagulation during dialysis the patient should be advised to press on the vaccination site for 5 mins after administration and given advice on action to take if significant bruising or swelling develops.

Table 1. Injection needle size for deltoid muscle administration

Patient weight	Needle length	Needle gauge
<80kg	16 / 25mm	23G
>80kg	25 / 38mm	21G

6.3 If patients develop a reaction or sensitivity to the vaccine, stop the course and refer to consultant or lead for BBV. Note that a reaction can occur after the second or third injection. Be aware that those with a known allergy to eggs, yeasts or who are asthmatic may be more likely to develop a reaction.

- 6.4 An anaphylaxis kit and CPR equipment must be available when administering the vaccine. Currently this should not be administered in the home environment.
- 6.5 If during the course of the injections one brand is not available, HB-Vax Pro and Engerix B can be interchanged during the same course of treatment as long as patient allergies do not prevent. Advice should be taken from BBV lead if prescriber is unsure.
- 6.6 Engerix B prescriptions should ideally be printed on yellow paper to differentiate between HBVaxPro.

Vaccination schedule

Table 2. HB-VaxPro (Sanofi Pastuer MSD)

Injection	Dose	Schedule months
1	40mcg in 1ml	0
2	40mcg in 1ml	1
3	40mcg in 1ml	6

Table 3. Engerix B (GlaxoSmithKline)

Injection	Dose	Schedule months
1	40mcg in 2ml	0
2	40mcg in 2ml	1
3	40mcg in 2ml	2
4	40mcg in 2ml	6

7. Monitoring and Follow-up

- 7.1 Eight weeks post completion of the prescribed course it is necessary to check response to the vaccine by testing for HBsAb titre levels. A response requires minimum levels of >10mIU/ml, but the preferred is >100mIU/ml.

Please note that up to 3 weeks after vaccination it is possible to have a false positive low level serum HBsAg result. Routine BBV testing should therefore be avoided in this period unless there is a clinical imperative to do so. Please indicate on the request form that vaccination has recently occurred to guide laboratory interpretation.

- 7.2 This vaccination procedure must occur in all a patients whether or not they are HBcAb positive.

- 7.3 Vaccination should however not be performed in patients who are HBsAg positive.

Table 4. Action to be taken at 8 weeks after first vaccination course.

Result	Response at 8 weeks	Action at 8 weeks	Follow-up
<10mIU/ml	No response	Repeat 2 nd full course	Check HBsAb 8 wks after last injection If still no response classified as non responder and for no further vaccination
10-100mIU/ml	Minimal response	Administer booster	Check HBsAb annually to guide further vaccination with further booster if levels drop below 100mIU/ml
>100mIU/ml	Good response	No action	Check HBsAb annually to guide further vaccination with further booster if levels drop below 100mIU/ml

- 7.4 A patient maybe HBsAg negative but already have an HBsAb response prior to renal immunisation programme. This may be because of:

- previous infection which has been cleared (may also be HBcAb positive)
- previous immunisation

- 7.5 These patients will not need a full course of vaccination and should be treated as below

Table 5. Action to take if patient HBsAb positive before renal vaccination programme

Result	Interpretation	Action	Follow-up
10-100mIU/ml	Minimal response	Administer booster	Check HBsAb annually to guide further vaccination with further booster if levels drop below 100mIU/ml
>100mIU/ml	Good response	No action	Check HBsAb annually to guide further vaccination with further booster if levels drop below 100mIU/ml

8. Special circumstances:

- If a patient is travelling to 'high risk' areas for dialysis they should receive a booster vaccination before leaving if HBsAb <100IU/ml in last sample.
- If there has been potential exposure to a Hepatitis B surface antigen positive patient in a dialysis related incident, and an accelerated vaccination course is deemed necessary by the BBV committee, then the accelerate course schedule should be used.

9. If a patient commences dialysis following a failing transplant or from another centre with HBsAb <10IU/ml and there is no record of a complete course of vaccination within the last 5 years, then it should be assumed vaccination has not occurred and protocols followed as such.

10. Responsibilities

10.1 Register Nurse

The Registered nurse will:

- Provide safe effective care for the patient requiring Hepatitis B vaccination;
- Provide the patient with knowledge and information on Hepatitis B and the available vaccination, in a way which the patient understands, in order that the patient can make an informed decision. This information must include the reasons for vaccination and the side effects. The patient should receive the appropriate UHB patient leaflet. 'Hepatitis B, Hepatitis C and HIV testing for people with chronic kidney disease or those on dialysis'; <http://www.uhb.nhs.uk/Downloads/pdf/PiHepatitisHivTestingCkd.pdf>
- Ensure the patient has provided verbal consent for sampling for BBV screening and has a clear understanding of the procedure and results. Record consent as per local procedure ensuring MARS renal database updated;
- Ensure that only patients that are HBsAg negative receive the vaccine;
- Ensure the patient is afebrile prior to administration, as pyrexia is a contraindication to the administration of Hepatitis B vaccination;
- Ensure the patient is not allergic to any of the vaccine contents. Those with a known allergy to latex cannot receive HBVaxPro;
- If known allergy to latex to administer Engerix B;
- Ensure the vaccine is administered according to the appropriate schedule.
- Document the administration of the vaccine on the Trust prescription and in the patient notes whether PICS or records of a partnership provider;
- Complete the patient's hand-held record;

- Record on MARSII renal database or inform satellite liaison team to facilitate;
- Ensure that 8 weeks after completion of the course of injections HBsAb levels are checked, and acted upon as per Table 4;
- Each unit must have a system in place guiding which patients are due annual review each month and then results are checked and vaccines administered as required; and
- Participation in the BBV clinical governance meeting if required

10.2 **Satellite Coordinator**

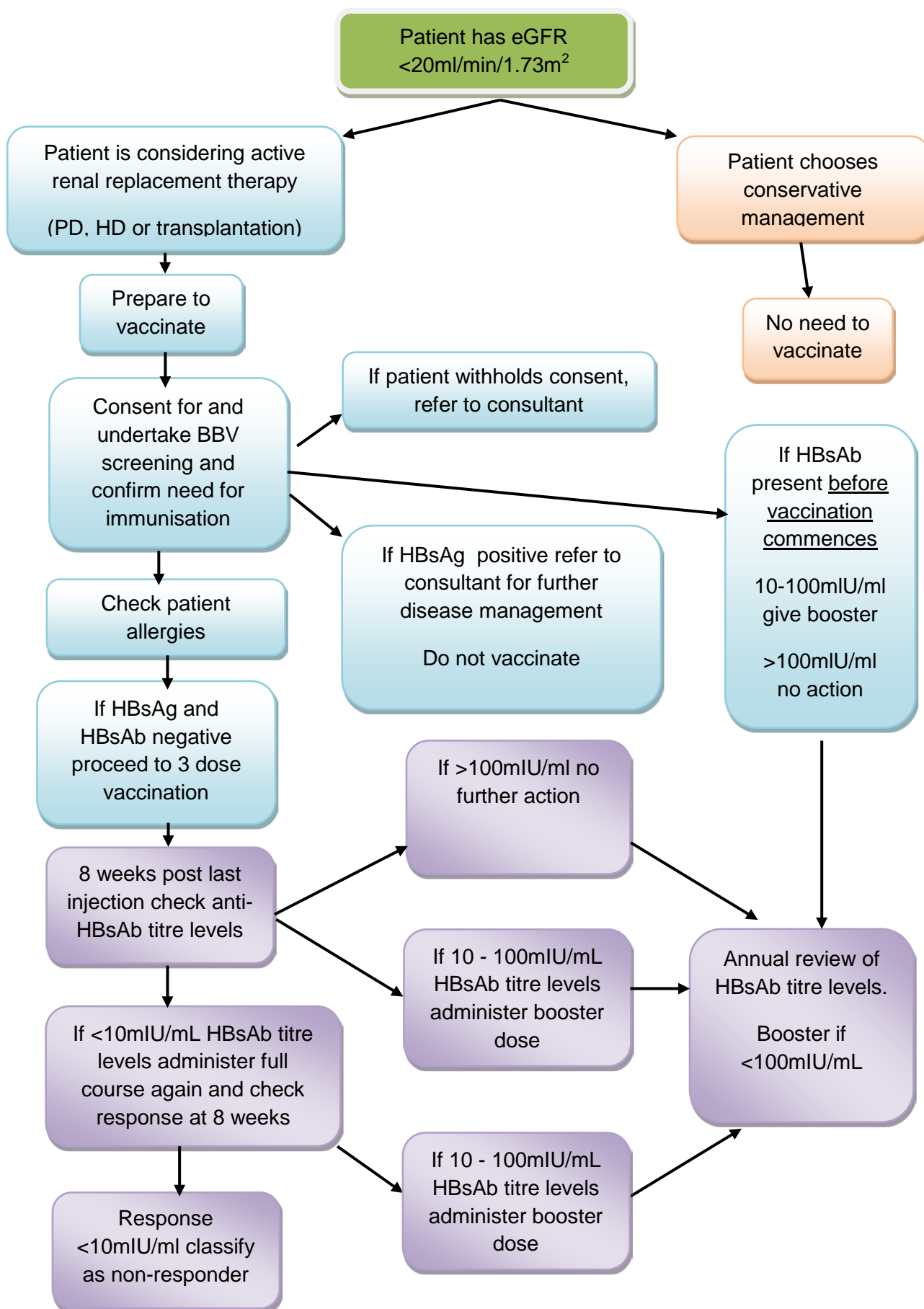
The Satellite Coordinator will:

- Work with dialysis link staff to co-ordinate the administration of vaccinations for patients receiving in-centre haemodialysis;
- Ensure prescriptions for Hepatitis B vaccinations are available at the appropriate time as requested by the units;
- Conduct an annual audit of vaccination and immunity amongst haemodialysis patients;
- Co-ordinate actions following 'rogue' results; and
- Present a quarterly report to the BBV Steering Committee, to include how many patients are immune, how many are not immune, how many patients require vaccination and the response to vaccinations.

10.3 **Medical Team**

Members of the Medical Team will:

- Support the nursing teams in ensuring all suitable patients are vaccinated and protected against Hepatitis B;
- If needed in addition to nursing education, ensure the patient has adequate knowledge and information prior to vaccination;
- Review the patient's medical history and allergies and appropriateness for immunisation as requested; and
- Prescribe Hepatitis B vaccination as requested.



11. Audit

A quarterly report is presented to the BBV Steering Committee; the report must include how many patients are immune, how many are not immune, how many patients require hepatitis vaccination and the response to vaccinations.

12. References

Department of Health (2002) **Good Practice Guidelines for Renal Dialysis/Transplantation Units, Prevention and Control of Blood-borne Virus Infection**, DOH, London.
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4059511.pdf [accessed 02.05.2012]

Mental Capacity Act 2005, <http://www.legislation.gov.uk/ukpga/2005/9/contents> [accessed 02.05.2012]

Renal Association (2009) **Blood Borne Virus Guidelines**
<http://www.renal.org/Clinical/GuidelinesSection/BloodBorneVirusInfection.aspx>
[accessed 02.05.2012]

University Hospitals Birmingham NHS Foundation Trust (current version) **Policy for consent to examination or treatment**, University Hospitals Birmingham NHS Foundation Trust.

GUIDELINES SUBMISSION DETAILS

Guidelines developed by:

Dr Clara Day	Consultant Nephrologist
Dr Peter Hewins	Consultant Nephrologist; chair BBV committee
Dr Erasmus Smit	Consultant Virologist
Matron Lucy Binns	Renal Matron
Sister Anne Marie Phythian	Renal Nurse
Sister Gabby Hadley	Renal Nurse

Renal Hepatitis B Immunisation Prescription

HBVaxPro

Name		DoB	
Hospital number		NHS number	

Allergies	
------------------	--

Pre vaccination status check (HBsAg and Anti-HBs)

Date checked	Result	Vaccinate Yes / No	Please tick
			<input type="checkbox"/> BBV verbal consent <input type="checkbox"/> Leaflet given <input type="checkbox"/> Recorded on MARS or <input type="checkbox"/> details sent to QE

HBVaxPro 40 is the brand of hepatitis B vaccination used by the Trust according to the following schedule.

inj	Vaccine	Route	Dose	Sched (mths)	Month Due	Date & time given	Temperature (°C)	Sign	Batch number
1	HBVaxPro 40	IM	40 micrograms in 1mls	0					
2	HBVaxPro 40	IM	40 micrograms in 1mls	1					
3	HBVaxPro 40	IM	40 micrograms in 1mls	6					

Dr's name (prescriber)	Drs Signature	Date

Check Hep B antibody titres (Anti-HBs) eight weeks after 3th dose

Date checked	Result	Outcome

Booster prescription

Drug	Route	Dose	Date & time given	Admin by Sign	Temp	Batch number
HBVaxPro 40	IM	40 micrograms in 1mls				

Dr's name (print)	Drs Signature	Date

Notes:

- Do not administer if pyrexial or if patient has allergy to latex or suffered a reaction to any prior doses
- Caution if allergic to eggs or known asthmatic
- Observe patient for 15 minutes after immunisation
- If patient is on haemodialysis -administer in last 30 mins or after dialysis as intra-muscular injection into upper arm (non-fistula arm)
- All vaccinations given must be recorded electronically in patient record and onto MARS
- Month due dates MUST not be changed; missed doses should be recorded as a drug omission

Renal Hepatitis B Immunisation Prescription

Engerix

Name		DoB	
Hospital number		NHS number	

Allergies	
------------------	--

Pre vaccination status check (HBsAg and Anti-HBs)

Date checked	Result	Vaccinate Yes / No	Please tick
			<input type="checkbox"/> BBV verbal consent <input type="checkbox"/> Leaflet given <input type="checkbox"/> Recorded on MARS or <input type="checkbox"/> details sent to QE

Engerix B is the brand of hepatitis B vaccination used by the Trust according to the following schedule.

inj	Vaccine	Route	Dose	Sched (mths)	Month Due	Date & time given	Temperature (°C)	Sign	Batch number
1	Engerix B	IM	40 micrograms in 2mls	0					
2	Engerix B	IM	40 micrograms in 2mls	1					
3	Engerix B	IM	40 micrograms in 2mls	2					
4	Engerix B	IM	40 micrograms in 2mls	6					

Dr's name (prescriber)	Drs Signature	Date

Check Hep B antibody titres (Anti-HBs) eight weeks after 4th dose

Date checked	Result	Outcome

Booster prescription

Drug	Route	Dose	Date & time given	Admin by Sign	Temp	Batch number
Engerix B	IM	40 micrograms in 2mls				

Dr's name (print)	Drs Signature	Date

Notes:

- Brand used if patient has latex allergy or HBVaxPro40 unavailable
- Do not administer if pyrexial or if patient suffered a reaction to any prior doses
- Caution if allergic to eggs or known asthmatic
- Observe patient for 15 minutes after immunisation
- If patient is on haemodialysis -administer in last 30 minutes or after dialysis into upper arm (non-fistula arm)
- All vaccinations given must be recorded electronically in patient record and onto MARS
- Month due dates MUST not be changed; missed doses should be recorded as a drug omission

Renal Hepatitis B immunisation Prescription (Accelerated Course)

HBVaxPro

Name		DoB	
Hospital number		NHS number	

Allergies	
------------------	--

Pre vaccination status check (HBsAg and Anti-HBs)

Date checked	Result	Vaccinate Yes / No	Please tick
			<input type="checkbox"/> BBV verbal consent <input type="checkbox"/> Leaflet given <input type="checkbox"/> Recorded on MARS or <input type="checkbox"/> details sent to QE

HBVaxPro 40 is the brand of hepatitis B vaccination used by the Trust according to the following schedule.

inj	Vaccine	Route	Dose	Sched (mths)	Month Due	Date & time given	Temperature (°C)	Sign	Batch number
1	HBVaxPro 40	IM	40 micrograms in 1mls	0					
2	HBVaxPro 40	IM	40 micrograms in 1mls	1					
3	HBVaxPro 40	IM	40 micrograms in 1mls	2					
4	HBVaxPro 40	IM	40 micrograms in 1mls	12					

Dr's name (prescriber)	Drs Signature	Date

Check Hep B antibody titres (Anti-HBs) eight weeks after 4th dose

Date checked	Result	Outcome

Booster prescription

Drug	Route	Dose	Date & time given	Admin by Sign	Temp	Batch number
HBVaxPro 40	IM	40 micrograms in 1mls				

Dr's name (print)	Drs Signature	Date

Notes:

- THIS ACCELERATED COURSE IS ONLY TO BE GIVEN IN SITUATIONS WHERE POSSIBLE EXPOSURE HAS OCCURRED WITH ADVICE FROM BBV CLINICAL LEAD**
- Do not administer if pyrexial or if patient has allergy to latex or suffered a reaction to any prior doses
- Caution if allergic to eggs or known asthmatic
- Observe patient for 15 minutes after immunisation
- If patient is on haemodialysis -administer in last 30 minutes or after dialysis into upper arm (non-fistula arm)
- All vaccinations given must be recorded electronically in patient record and onto MARS
- Month due dates **MUST** not be changed; missed doses should be recorded as a drug omission

Appendix 2 – Vaccination Cards

- [Hepatitis B vaccination card \(CKD team\)](#)
- [Hepatitis B vaccination card \(Satellite Dialysis team\)](#)
- [Hepatitis B vaccination card \(reverse\)](#)