This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Hepatitis B Recombinant DNA (rDNA) Vaccine (adsorbed)

By registered health care professionals for

Individuals considered at increased risk of exposure to Hepatitis B Virus, at increased risk of complications of Hepatitis B Disease, or Post Potential Exposure to Hepatitis B Virus.

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 136

1. Change history

Version number	Change details	Date
V01.00	New PHE PGD template	29/03/2017
V02.00	HepB PGD amended to: • include additional healthcare practitioners in Section 3 • include HBvaxPRO® temperature excursion stability • refer to vaccine incident guidelines in off-label and storage sections • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	12/03/2019

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy • Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises **Additionally practitioners:** • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the 'cold chain' • must be competent in the recognition and management of anaphylaxis Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD)
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals considered at increased risk of exposure to hepatitis B virus, at increased risk of complications of hepatitis B disease, or after a potential exposure to hepatitis B virus in accordance with the recommendations given in Chapter 7 and Chapter 18 of Immunisation Against Infectious Disease: 'The Green Book'
Inclusion criteria	**Post-exposure** Individuals who: • are babies born to hepatitis B infected mothers • have been potentially exposed to hepatitis B infected blood or body fluids **Pre-exposure** Individuals who: • have chronic liver disease (for instance those who have severe liver disease, such as cirrhosis of any cause, or have milder liver disease and may share risk factors for acquiring hepatitis B infection, such as individuals with chronic hepatitis C) • receive regular blood or blood products (for example individuals with thalassaemia, haemophiliacs, or carers who administer such products) • inject drugs or those who are likely to progress to injecting (see Chapter 18) • are sexual partners, children, or other close family or household contacts of people who inject drugs (PWID) • change sexual partners frequently, are men who have sex with men (MSM) or commercial sex workers • are household, close family or sexual contacts of an individual with hepatitis B infection • are members of a family adopting children from countries with a high or intermediate prevalence of hepatitis B • are, or are close family or household of, short-term foster carers who receive emergency placements • are, or are close family or household of, permanent foster carers who accept a child known to be hepatitis B infected • are inmates of custodial institutions in the UK, including those on remand • are resident in accommodation for those with learning disabilities • are adults or children attending day care, schools and centres for those with learning disabilities and, based on local risk assessment, are at risk of frequent percutaneous exposure (such as biting or being bitten)

Exclusion criteria	Individuals for whom no valid consent has been received. Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of hepatitis B containing vaccine or to any components of the vaccine • are known to have markers of current (HBsAg) or past (anti-HBcore) hepatitis B infection
Cautions (including any relevant action to be taken)	• Premature infants should have their immunisations at the appropriate chronological age, according to the schedule. This is vital for infants born to hepatitis B infected mothers as delay will increase the chance of infection being acquired. However, the occurrence of apnoea following vaccination is especially increased in infants who were born very prematurely. Therefore, very premature infants (born ≤ 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hours. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed • Syncope (fainting) can occur following, or even before any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints • Use caution when vaccinating individuals with severe (ie anaphylactic) allergy to latex. The HBvaxPRO® syringe plunger, stopper and tip cap contain dry natural latex rubber; use an alternative vaccine if available • The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded *(continued)*	• Patient should be referred to a more experienced clinical practitioner for further assessment • Individuals who have had a confirmed anaphylactic reaction to a previous dose of HepB vaccine or any components of the vaccine should be referred to a clinician for specialist advice and appropriate management. • Individuals known to have markers of current (HBsAg) or past

Action to be taken if patient excluded *(continued)*	(anti- HBcore) hepatitis B infection should be advised that vaccination is not necessary. However, immunisation should not be delayed while awaiting any test results • Individuals who are on haemodialysis, or renal transplantation programmes, or with chronic kidney disease and anticipated to require haemodialysis or transplant should be offered HepB vaccination but this is outside the remit of this PGD (see HepB Renal PGD for vaccination of renal patients over 15 years, or for individuals under 15 years refer for specialist advice and manage under PSD as appropriate) • Individuals requiring HepB vaccination solely for overseas travel purposes should be administered HepB in accordance with local policy. However, HepB immunisation for travel is not remunerated by the NHS as part of additional services and is therefore not covered by this PGD. Where an individual also requires HepA vaccination, it may be appropriate to provide the combined HepA and HepB vaccine, see the PHE HepA/B vaccine PGD • Individuals who are solely at occupational risk of hepatitis B exposure should be referred to their employer's occupation health provider for vaccination • Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged • Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required • The risk to the individual of not being immunised must be taken into account • Document the reason for exclusion and any action taken in the individual's clinical records • In a GP practice setting, inform or refer to the GP or a prescriber as appropriate
Action to be taken if patient declines treatment *(continued)*	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration • Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications

Action to be taken if patient declines treatment *(continued)*	• All cases where HepB vaccination is declined on behalf of infants born to hepatitis B positive mothers should be contemporaneously referred • In a GP practice setting, inform or refer to the GP as appropriate

8. Details of the medicine

Name, form and strength of medicine	Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed)* (HepB) eg: • Engerix B® 10micrograms/0.5ml suspension for injection in pre- filled syringe • Engerix B® 20micrograms/1ml suspension for injection in pre- filled syringe • Engerix B® 20micrograms/1ml suspension for injection in a vial • HBvaxPRO® 5micrograms/0.5ml suspension for injection in pre- filled syringe • HBvaxPRO® 10micrograms/1ml suspension for injection in pre- filled syringe An appropriate vaccine product should be selected for the patient group to be treated see Dose and Frequency of Administration
Legal category	Prescription only medicine (POM)
Indicate any off-label use (if relevant)	• The full 1ml volume of adult preparations of HepB vaccine may be given to paediatric patients off-label, during paediatric hepatitis B containing vaccine supply shortages, in accordance with the PHE recommendations, see Hepatitis B: vaccine recommendations during supply constraints • Engerix B® very rapid (super accelerated) schedule (given at 0, 7 and 21 days) is licensed for those from 18 years of age but may be used off-label in those from 16 to 18 years of age where it is important to provide rapid protection and to maximise compliance (this includes PWID and those in prison) in accordance with Chapter 18 of 'The Green Book' • Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD • Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence

<table>
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<td>Route/method of administration
(continued)</td>
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Administer by intramuscular injection into the deltoid region of the upper arm for individuals over one year of age and the anterolateral thigh for infants. The buttock should not be used because vaccine efficacy may be reduced
When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each was given should be noted in the individual's records
For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneousinjection to reduce the risk of bleeding (see 'The Green Book' Chapter 4).The vaccine may settle during storage, shake the vaccine well before administration to obtain a slightly opaque (HBvaxPro®) or turbid (Engerix B®), white suspension
The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.
The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk

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<tr>
<td>Dose and frequency
(continued)</td>
<td>
Individuals who require other vaccines at the same time as a scheduled HepB dose may receive these as separate vaccine products or the scheduled HepB dose may be fulfilled by the administration of a multivalent vaccine, eg HepA/HepB combined vaccine or DTaP/IPV/Hib/HepB, see PHE HepA/B vaccine PGD or PHE DTAP/IPV/Hib/HepB PGD as appropriate.

Current UK licensed HepB vaccines contain different concentrations of antigen per millilitre.

Table 1: Current UK licensed HepB vaccine doses
<table>
<tr><th>Age</th><th>Vaccine</th><th>Dose</th><th>Volume</th></tr>
<tr><td rowspan="2">0–15 years*</td><td>Engerix B®**</td><td>10 micrograms</td><td>0.5ml</td></tr>
<tr><td>HBvaxPRO®**</td><td>5 micrograms</td><td>0.5ml</td></tr>
<tr><td rowspan="2">16 years or over</td><td>Engerix B®</td><td>20* micrograms</td><td>1.0ml</td></tr>
<tr><td>HBvaxPRO®</td><td>10 micrograms</td><td>1.0ml</td></tr>
</table>

It is important for immunisations to be provided on time as delay will increase the chance of infection being acquired (see Table 2 for schedules). Where immunisation has been delayed beyond the recommended intervals, the vaccine course should be resumed and completed.
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Dose and frequency *(continued)*

Table 2: Pre- and post-exposure prophylaxis schedules for Engerix B® or HBvaxPRO®

Schedule	Examples of when to use this schedule
Usual pre- and post- exposure prophylaxis accelerated schedule*: 3 doses at 0, 1, and 2 months further dose 12 months after the first dose for babies born to hepatitis B positive mothers and individuals at continued risk	• Used for individuals of all ages for pre- and post-exposure prophylaxis • This is the preferred schedule for babies born to hepatitis B positive mothers. Note: dose from 2 months of age may be provided by multivalent vaccine, eg DTaP/IPV/Hib/ HepB, and doses may also be administered in addition to this schedule where DTaP/IPV/Hib/HepB is used for routine childhood immunisation
Alternative schedule*: • 3 doses at 0, 1, and 6 months	This is rarely the most appropriate schedule. It should only be used when rapid protection is not required and there is a high likelihood of compliance with the regimen
Two dose schedule of Engerix B® only: • 2 doses of adult strength (20 microgram) vaccine at 0 and 6 months	Only to be used for individuals 11 to 15 years of age, when there is a low risk of hepatitis B infection during the course and completion of the course can be assured
Very rapid (super accelerated) schedule of Engerix B® only: • 3 doses at 0, 7 days and 21 days • further dose 12 months after the first dose is recommended to be considered protected	To be used for individuals from 16 years of age (see Off-label use) who are at immediate risk and when very rapid immunisation is required eg PWID, prisoners
Booster (Engerix B®, HBvaxPro®)*: Single dose administered 5 years after the primary course or, for children born to hepatitis B infected mothers, given with the pre-school boosters** for other childhood immunisations	Use once to maintain immunity for those who continue to be at risk **Note: Children born to hepatitis B infected mothers who have received five or more HepB doses, from either

<table>
<tr><td>Dose and frequency
(continued)</td><td>
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<tr><td></td><td>monovalent or multivalent vaccine (eg DTaP/IPV/Hib/ HepB), including one dose from 12 months of age, do not routinely require a further HepB booster with their pre-school vaccinations</td></tr>
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*HBvaxPRO® and Engerix B® may be used interchangeably to complete the vaccine course.

Note: Scheduled HepB vaccine doses may be fulfilled by multivalent vaccine when appropriate. This PGD does not cover the administration of multivalent vaccines.
</td></tr>
<tr><td>Quantity to be administered and/or supplied</td><td>Dose of 0.5ml or 1.0ml per an administration depending on the age of the individual and vaccine product used, see Dose and frequency of administration</td></tr>
<tr><td>Maximum or minimum treatment period</td><td>Dependent on vaccine schedule, see Dose and frequency of administration</td></tr>
<tr><td>Storage</td><td>

Store at between +2°C to +8°C
Store in original packaging in order to protect from light
Do not freeze
In the event of an unavoidable temperature excursion. HBvaxPRO® can be administered provided total (cumulative multiple excursion) time out of refrigeration (at temperatures between 8°C and 25°C) does not exceed 72 hours. Cumulative multiple excursions between 0°C and 2°C are also permitted as long as the total time between 0°C and 2°C does not exceed 72 hours
In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to PHE Vaccine Incident Guidance

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<tr><td>Adverse effects</td><td>

Local reactions following vaccination are very common ie pain, swelling or redness at the injection site, induration
Low grade fever, fatigue, drowsiness, headache, irritability, appetite loss and gastrointestinal symptoms (nausea, vomiting, diarrhoea, and abdominal pain) have been commonly reported symptoms after HepB vaccination
Hypersensitivity reactions and anaphylaxis can occur but are very rare
A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

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<tr><td>Records to be kept</td><td>

The administration of any medication given under a PGD must be recorded within the patient's medical records
See Appendix C for more information

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9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request • Immunisation promotional material may be provided as appropriate: • A guide to immunisations up to one year of age • Hepatitis B: what does my positive screening result mean? Available from: www.gov.uk/government/collections/immunisation
Follow-up advice to be given to patient or carer	• Inform the individual/carer of possible side effects and their management • The individual/carer should be advised to seek medical advice in the event of an adverse reaction • When administration is postponed advise the individual/carer when to return for vaccination • Sexual contacts of individuals infected with hepatitis B should be advised regarding the appropriate use of condoms; a reasonable level of protection can be assumed following the second dose, provided that completion of the schedule can be assured • Individuals/carers should be informed about the importance of completing a course of hepatitis B immunisation. Hepatitis B positive mothers whose babies are on the neonatal hepatitis B immunisation pathway should be informed of the importance of completing the course on time and for baby to be tested at age 12 months to identify if they have become chronically infected with hepatitis B

10. Appendix A

References

1. British National Formulary (BNF) 2019 available online: https://bnf.nice.org.uk
2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: https://www.medicines.org.uk

HepB Vaccine

- Immunisation Against Infectious Disease: The Green Book Chapter 4, last updated June 2012, Chapter 18, last updated 17 July 2017. https://www.gov.uk/government/collections/immunisation-against- infectious-disease-the-green-book
- Summary of Product Characteristic for Engerix B®, GlaxoSmithKline. 24 April

2017.http://www.medicines.org.uk/emc/medicine/9283
http://www.medicines.org.uk/emc/medicine/24844
- Summary of Product Characteristic for HBvaxPRO® 5mcg and 10mcg. MSD Ltd. 12 March 2019. http://www.medicines.org.uk/emc/medicine/9850
http://www.medicines.org.uk/emc/medicine/9847
- NHS public health functions agreement 2018-19, Service specification No.1 Neonatal hepatitis B immunisation programme. September 2018.
https://www.england.nhs.u/publication/public-health-national-service-specifications/
- Hepatitis B: vaccine recommendations during supply constraints. Public Health England, last updated 20 November 2018. https://www.gov.uk/government/publications/hepatitis-b-vaccine- recommendations-during-supply-constraints
- Exposure to hepatitis B virus: guidance on post-exposure prophylaxis. PHLS Hepatitis Subcommittee. 14 August 1992.
http://webarchive.nationalarchives.gov.uk/+/http://www.hpa.org.uk/cdr/archives/CDRreview/1992/cdrr0992.pdf

General

- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe- management-of-healthcare-waste
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for- registered-healthcare-practitioners
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017.https://www.nice.org.uk/guidance/mpg2/resources
- PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation
- PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident- guidance-responding-to-vaccine-errors
- Protocol for ordering storage and handling of vaccines. April 2014.
https://www.gov.uk/government/publications/protocol-for-ordering- storing-and-handling-vaccines

11. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

12. Appendix C

Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013)
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Records to be kept	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) • Records should be signed and dated (or a password controlled immunisers record on e-records) • All records should be clear, legible and contemporaneous • This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate • health records should be kept and the individual's GP informed • The local Child Health Information Services team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement • A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy

Special considerations/ additional information *(continued)*	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. **Limitations of HepB vaccination** Because of the long incubation period of hepatitis B it is possible for unrecognised infection to be present at the time of immunisation. The vaccine may not prevent hepatitis B infection in such cases. The vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis A, hepatitis C and hepatitis E viruses. As with any vaccine, a protective immune response may not be elicited in all vaccines (see Chapter 18 for more detail). **Testing for evidence of infection or immunity** Where testing for markers of current or past infection is clinically indicated (eg sexual and household contacts of hepatitis B infected individuals), this should be done at the same time as the administration of the first HepB vaccine dose. Vaccination should not be delayed while waiting for results of the tests. Further doses may not be required in those with clear evidence of current or past infection. Testing children born to hepatitis B infected mothers for HBsAg at one year of age will identify any babies for whom vaccination has not been successful and who have become chronically infected with hepatitis B, and will allow them to be referred for assessment and any further management. This testing can be carried out at the same time as the 12 month vaccine dose is given. Where immunisation has been delayed beyond the recommended intervals, the vaccine course should be completed, but it is more likely the child may become infected. In this instance, testing for HBsAg from 12 months of age is particularly important. Additional vaccine doses may need to be considered for persons who do not respond or have a sub-optimal response to a course of vaccinations. Except in certain groups (eg risk of occupational exposure and renal failure), testing of anti-HBs is not routinely recommended. Refer to Chapter 18 for advice on response to vaccine and the use of additional doses. The 1ml adult preparations of HepB vaccine contain exactly twice the content of the paediatric equivalent (see Table 1 above). As the adult pre-filled syringe has no clear graduations, PHE recommends that the full 1ml volume (ie an adult dose) should be given to avoid the risk of under-dosing the child (see doses and volumes in Table 1 above). This

Special considerations/ additional information *(continued)*	will be off-label use of the adult vaccine. Available data, although limited, does not indicate any additional safety risk from use of adult HepB vaccine in infants. If an adult dose(s) of HepB vaccine has been used in a child, the course can be completed with paediatric products at the appropriate ages when vaccine stock becomes available. **Pregnant women/breastfeeding** There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated vaccines. Since HepB is an inactivated vaccine, the risks to the foetus are negligible and it should be given where there is a definite risk of infection.