Public Health England

NHS England

Yorkshire and the Humber

PATIENT GROUP DIRECTION (PGD)

Administration of **Hepatitis B** recombinant DNA (rDNA) vaccine (adsorbed) to 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.

This PGD is for the administration of **Hepatitis B Vaccine** (rDNA) vaccine (adsorbed) **(Engerix B® and HBvaxPRO®)** to eligible patients in line with national guidance by currently registered nurses or midwives employed by providers commissioned by or on behalf of NHS England – North (Yorkshire and the Humber)

Reference: Hepatitis B Vaccine (Engerix B® and HBvaxPRO®)

Version no: **01.00**

Valid from: **22nd September 2017**

Review date: **01 May 2019**

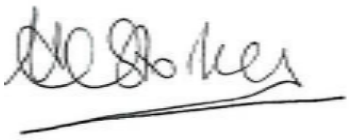
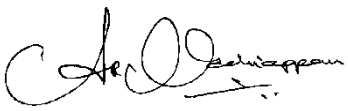
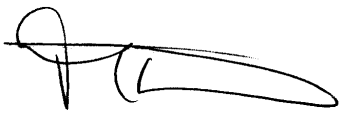
Expiry date: **31 August 2019**

The PGD has been authorised following NHS England's governance processes so that it meets the legal requirements for a PGD. Each provider organisation using this PGD should formally adopt it via a signature from the provider's governance lead or lead practitioner. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Practitioners intending to work under the PGD must be individually authorised by their/the designated manager, under the current version of this PGD before working according to it. Each practitioner is professionally accountable for ensuring they have undergone appropriate training and are competent and understand the contents of this PGD and the requirements of the individual vaccine programme, including route of administration, contra-indications etc.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of Yorkshire and the Humber PGDs can be found from: https://www.england.nhs.uk/north/our-work/pgds/

1. PGD Development Team

Developed & Produced by:	Name of Developer, Job Title and Employing Organisation	Signature	Date
Senior Pharmacist	Hilde Storkes Medicines Governance Pharmacist NHS Sheffield CCG		**18/09/17**
Doctor (Lead Author)	Dr Nachi Arunachalm Consultant in Communicable Disease Control PHE Health Protection Team Yorkshire and the Humber Centre		**19.9.17**
Senior Registered Nurse	Mary Law Screening and Immunisation Manager (on behalf of NHS England North - Yorkshire & the Humber)		**15.9.17**

Acknowledgements (this may include representatives from CCG Medicine Management Teams who have contributed via consultation)

Name	Designation
Kathy Wakefield	Senior Screening and Immunisation Manager (on behalf of NHS England North - Yorkshire & the Humber)
Y&H PGD Steering Group	

2. Version Control

Version number	Change details	Date
V01.00	New Y&H PGD template	01/09/2017

3. Organisational Authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met.

Approved by:	*Name and Job Title*	*Signature*	*Date*
NHS England – North	Paul Twomey Medical Director Yorkshire and the Humber		**21.09.17**

Adoption for use by the provider organisation is recommended as part of good clinical governance (to be determined locally if relevant i.e. may not be applicable if independent single pharmacy)

Name of Provider Organisation	**Name of Person accepting on behalf of provider organisation (please print)**	**Designation of Person accepting on behalf of provider organisation (please print)**	**Signature of Person accepting on behalf of provider organisation**	**Date**

4. Characteristics of Staff

Qualifications and professional registration	Registered Nurse or Registered Midwife currently registered with the Nursing and Midwifery Council (NMC) contracted to or on behalf of the NHS England North (Yorkshire and the Humber) and who has completed a relevant immunisation training programme recognised by their employing organisation. This should ideally be in accordance with the HPA National Minimum Standards for Immunisation Training (2005).
Additional requirements	Additionally practitioners must: • be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • have access to the Patient Group Direction and associated online resources • be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics; Immunisation Against Infectious Disease (hereafter referred to as "The Green Book"); and national and local immunisation programmes • have undertaken training appropriate to this PGD as required by local policy • be competent to undertake immunisation and to discuss issues related to immunisation • be competent in the handling and storage of vaccines, and management of the "cold chain" • be competent in the recognition and management of anaphylaxis • be familiar with their employing organisations' policy on the management of anaphylaxis for adults and children. If the employing organisation does not have such a policy/protocol then vaccination under this PGD is not permitted. • fulfil any additional requirements defined by local policy **THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.** Knowledge of and access to: • *Resuscitation Council (UK) (2008/Annotated 2012): Emergency treatment of anaphylactic reactions* http://www.resus.org.uk/pages/reaction.htm • *NICE (2011): Clinical Guideline 134. Anaphylaxis* http://guidance.nice.org.uk/CG134 • *Summary of Product Characteristics (SPC)* for Engerix B® and HBvaxPro® available from: http://www.medicines.org.uk/emc/ • *Patient Information leaflet (PIL)* for Engerix B® and HBvaxPro® available from: http://www.medicines.org.uk/emc/ • *The Code for nurses and midwives* - Professional standards that nurses and midwives must uphold to be registered to practice in the UK https://www.nmc.org.uk/standards/code/ • *Standards for Medicines Management* https://www.nmc.org.uk/standards/additional-standards/standards-for-medicines-management/ • The Green Book relevant updates and compliance with its recommendations • CCG or individual organisation's consent policy • *NICE Medicines Practice Guidelines 2* (2013 updated Mar 2017): Patient Group Directions – Section 1.5 Using patient group directions https://www.nice.org.uk/guidance/mpg2/chapter/Recommendations

Continued training requirements	• 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) • Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information • Annual vaccination and immunisation updates are recommended for all staff involved in immunisation in line with national guidance • Annual updates on resuscitation skills for adults and children (including defibrillation training where defibrillator is available) and the management of anaphylaxis within the community *The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria in this PGD.*

5. Clinical condition or situation to which the direction applies

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 The Green Book
Criteria for inclusion	The PGD covers administration to the following groups of patients who are at high risk of hepatitis B: **Post-exposure** Individuals who: • Are babies born to hepatitis B positive/infected mothers **Pre-exposure** Individuals who: • Are receiving regular blood or blood products, e.g. individuals with thalassaemia, haemophiliacs, or carers who administer such products • Inject drugs or those who are likely to progress to injecting (see Chapter 18 of The Green Book • 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 close family contacts of a case or individual with chronic 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 at high risk of hepatitis B/hepatitis B infected • Are in residential accommodation for those with learning difficulties. • Are inmates of custodial institutions in the UK, including those on remand • 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 (e.g. biting or being bitten) **Locally commissioned** The following categories for pre-exposure immunisation are included ***only where these are locally commissioned*** (check with medicines management team if uncertain): • Individuals who are from communities with a high prevalence of hepatitis

	B infection • People travelling overseas: hepatitis B immunisation is not remunerated by the NHS as part of additional services; the GP practice may therefore charge administration to those solely at risk due to travel as a private service. This PGD does not authorise private administration. The following groups of travellers to areas of intermediate to high prevalence*, who place themselves at risk when abroad, may be administered under this PGD as an NHS service where locally commissioned: ○ who are at risk due to sexual activity or injectable drug use ○ who undertake relief aid work ○ who participate in contact sports ○ those who will be travelling/residing in areas of high or intermediate prevalence for lengthy periods ○ children and others who may require medical care while travelling to visit families and relatives in high or moderate endemicity countries ○ people with chronic medical conditions who may require hospitalisation while overseas e.g. dialysis who are at high risk of requiring medical or dental procedures in countries using unsafe therapeutic injections (e.g. reuse of contaminated needles and syringes without sterilisation) *information available from: Travel Health Pro hepatitis B factsheet and Chapter 18 of The Green Book
Criteria for Exclusion	• Individuals for whom no valid consent has been received. **Individuals who:** • Do not meet inclusion criteria • 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 • Are on haemodialysis, renal transplantation programmes or have chronic renal failure • Have chronic liver disease (i.e. 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) • Require hepatitis B vaccination solely for the purpose of overseas travel, unless local commissioned. • Are at solely an occupational risk of hepatitis B exposure • Post exposure immunisation for persons: ➢ who are accidentally contaminated or inoculated with blood (e.g. needle stick injury) or exposed to body fluids ➢ who have had unprotected sexual intercourse • Are suffering from acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation) • Have had a severe general or local reaction or confirmed anaphylactic reaction to a previous dose or to any component of this vaccine • Have a confirmed anaphylactic reaction to latex • Have an allergy to formaldehyde and potassium thiocyanate - applicable to HBvaxPRO® as these substances are used in the manufacturing process and trace residues may remain • Patients with unknown immunisation status
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 positive/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 (i.e. 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. • Minor illness, without fever or systemic upset, is not a valid reason 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 signs or symptoms to adverse effects of the vaccine. • As with any vaccine, vaccination with hepatitis B may not result in complete protection in all recipients. A number of factors have been observed to reduce the immune response including older age, male gender, obesity, smoking, route of administration and some chronic underlying diseases, including HIV infection. **Pregnancy and breast feeding**: There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids. Immunisation with hepatitis B vaccine should not be withheld where there is a clinical need and the benefit is considered to outweigh the risk.
Action to be taken if excluded	• Individuals who have had a confirmed anaphylactic reaction to a previous dose of hepatitis B 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 (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 hepatitis B vaccination but this is outside the remit of this 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 with chronic liver disease should have an individual assessment and be vaccinated using a PSD • 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 or deferrals and any action taken in the individual's clinical records • Consider informing or referring to medical practitioner. In a GP practice setting inform or refer to the GP or a prescriber as appropriate • Post exposure immunisation following accidental exposure or unprotected sexual intercourse should, after assessment by a medical practitioner, be administered under a PSD • If excluded due to unknown immunisation status the individual should have an individual assessment and be vaccinated using a PSD • For severe general or local reactions refer to GP who may wish to discuss further with the Consultant in Communicable Disease Control (CCDC) (contact details below) • For a confirmed anaphylactic reaction to latex, undertake a risk assessment and refer to GP, who may wish to discuss further with the CCDC (contact details below). Further information is also available in Chapter 6 of The Green Book • For children under the age of 19 years inform the Child Health Record Department The CCDC may be contacted at the local Public Health England Health Protection Team via the Acute Response Centre (ARC): **Contact Number: 0113 3860 300** If the ARC is busy your call will be diverted to admin staff in any of the 3 regions Sheffield, York or Leeds, they will take a message and get the ARC to return your call as soon as possible.
Action if patient or carer declines treatment/vaccination	• 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 • Inform or refer to medical practitioner if patient declines treatment. • All cases where hepatitis B vaccination is declined on behalf of infants born to hepatitis B positive/infected mothers should be immediately referred to the GP • If child under the age of 19 years inform Child Health Records Department • Document advice given and the decision reached in clinical records
Arrangements for referral for medical advice	As per local policy

6. Description of Treatment

Name, strength & formulation of drug	Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed)* (HepB) • 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 Section: Dose and Frequency of Administration)*
Legal Status	Prescription only medicine (POM)
Black Triangle▼	No
Off label use	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 included in Vaccine Update 248 (June 2016) and Hepatitis B vaccination in adults and children: temporary recommendations from 21 August 2017 available from Hepatitis B: vaccine recommendations during supply constraints Engerix B® rapid schedule is licensed for those from 18 years of age but may be used off-label in those from 16 to 18 years of age (see **Super-accelerated schedule in Table 2)** where it is important to provide rapid protection and to maximise compliance (e.g. PWID and those in prison) in accordance with Chapter 18 of The Green Book. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route/method of administration	Administer by intramuscular injection into the upper arm or anterolateral thigh. The buttock must 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 subcutaneous injection to reduce the risk of bleeding (see Chapter 4 of The Green Book). Under no circumstances should it be given intravascularly or intradermal. 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. *Further information and guidance on administration is available from:* • *The vaccine's Summary of Product Characteristics (SPC) from the electronic Medicines Compendium website* • *Chapter 4 of The Green Book*
Dose and frequency of administration *(This section is reproduced in Appendix A for*	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, e.g. HepA/HepB combined vaccine or DTaP/IPV/Hib/HepB, as appropriate. *The administration of multivalent vaccine is outside the remit of this PGD*.

clarity and ease of reference)

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

Table 1: Current UK licensed HepB vaccine doses

Age	**Vaccine**	**Dose**	**Volume**
0–15 years*	Engerix B®**	10 micrograms	0.5ml
	HBvaxPRO®**	5 micrograms	0.5ml
16 years or over	Engerix B®	20* micrograms	1ml
	HBvaxPRO®	10 micrograms	1ml

*20 micrograms of Engerix B® may be given to children 11-15 years of age if using the two dose schedule.

**During supply shortages of paediatric hepatitis B containing vaccine, the full 1ml adult preparation of hepatitis B containing vaccine may be administered to infants (off-label) rather than delay or risk omitting HepB vaccination in individuals at high risk *(see Section: Special considerations / additional information).* The adult preparations may be used interchangeably with the paediatric products when vaccine becomes available *(see Section: Special considerations / additional information for order of preference).*

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.

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/infected 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/infected mothers. *Dose from 2 months of age may be provided by multivalent vaccine, e.g. 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.
Super-accelerated schedule of Engerix B® only: • 3 doses at 0, 7 days	To be used for individuals from 16 to 18 years of age *(see Section: Off-label use)* where it is important to provide rapid protection and to maximise compliance i.e.

	and 21 days • further dose 12 months after the first dose is recommended to be considered protected	those who are at immediate risk and when very rapid immunisation is required e.g. PWID and those in prison) in accordance with Chapter 18 of The Green Book.
	Booster (Engerix B®, HBvaxPro®)*: • Single dose administered 5 years after the primary course or, • for children born before 01/08/2017 to hepatitis B positive/infected mothers given with the pre-school boosters**	Use once to maintain immunity for those who continue to be at risk.

**HBvaxPRO® and Engerix B® may be used interchangeably to complete the vaccine course.*

*** Children born to hepatitis B positive/infected mothers who have received five or more HepB doses, from either monovalent or multivalent vaccine (e.g. 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.*

Scheduled HepB vaccine doses may be fulfilled by multivalent vaccine when appropriate.

This PGD does not cover the administration of multivalent vaccines.

Reinforcing immunisation

For people who travel overseas who have completed a primary course of vaccination, a single booster dose of vaccine at five years is not routinely required; however if further travel is planned a new travel risk assessment should be undertaken

Duration of treatment	Dependent on vaccine schedule *(see Section: Dose and Frequency of Administration)*
Quantity to be supplied / administered	Dose of 0.5ml or 1ml per an administration depending on the age of the individual and vaccine product used *(see Section: Dose and Frequency of Administration)*
Supplies	Supplies should be ordered directly from manufacturers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Chapter 3 of The Green Book)
Storage	• Store in a vaccine refrigerator at between +2°C to +8°C. • Store in original packaging in order to protect from light. • Do not freeze. The storage of vaccines must comply with the Public Health England protocol for ordering, storing and handling vaccines, updated March 2014.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant 'sharps' box with yellow coloured lid, according to local authority regulations and guidance in the Health Technical Memorandum (HTM 07-01) guide for those involved in the management and disposal of healthcare waste (DH 2013).

Drug Interactions	• Hepatitis B vaccine must not be mixed with any other vaccine in the same syringe. • Immunological response may be diminished in those receiving immunosuppressive treatment. • May be given at the same time as other vaccines. *Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list: http://www.medicines.org.uk/emc/*
Identification & management of adverse reactions	• Local reactions following vaccination are very common i.e. 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. *Refer to BNF and SPC for complete list: http://www.medicines.org.uk/emc* Advice is available from: • The screening and immunisation coordinator within the Screening and Immunisation Team • Consultant in Communicable Disease Control (CCDC) at your local Public Health England Health Protection Team **Contact Number: 0113 3860 300**
Reporting procedure of adverse reactions	Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed. All vaccine related incidents must be reported to the Screening and Immunisation Team at NHS England.
Written information to be given to patient or carer	Offer marketing authorisation holder's Patient Information Leaflet (PIL) provided with the vaccine. 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?
Advice to patient / carer and follow up treatment	• The purpose and benefits of immunisation. • 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. • Frequency of follow-up treatment • 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/infected 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

Special considerations and additional information	**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 vaccinees (see Chapter 18 of The Green Book for more detail). **Testing for evidence of infection or immunity** Where testing for markers of current or past infection is clinically indicated (e.g. 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 positive/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 that 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 (e.g. risk of occupational exposure and renal failure), testing of anti-HBs is not routinely recommended (see Chapter 18 of The Green Book for advice on response to vaccine and the use of additional doses). **Post-exposure prophylaxis** *See Chapter 18 of The Green Book* **Hepatitis B Immunoglobulin (HBIG)** *This PGD does not cover the administration of HBIG.* **Choice of HepB vaccine** During periods of constrained paediatric hepatitis B containing vaccine, the first priority group for paediatric vaccine should be infants in the selective neonatal hepatitis B programme, i.e. infants born to hepatitis B positive/infected mothers receiving post exposure prophylaxis (PEP), followed by other lower risk indications for PEP. Vaccine administration should never be delayed for infants born to hepatitis B positive/infected mothers, as these infants have been exposed to a substantial volume of infectious blood during the birthing process. Available vaccine products should be used in the following order of preference: **1.** Hepatitis B paediatric monovalent vaccine (Engerix B® 10 microgram in 0.5ml or HBvaxPRO® 5 micrograms in 0.5ml) **2.** Hepatitis B adult monovalent vaccine (Engerix B® 20 micrograms in 1ml and HBvaxPRO® 10 micrograms in 1ml). **3.** Combined hepatitis A and B vaccine (administration of this vaccine is not covered by this PGD).

	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 (i.e. an adult dose) should be given to avoid the risk of under-dosing the child (see 'doses and volumes' in Table 1 above). This 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. **Anaphylaxis** As with most vaccines, anaphylactic reactions are extremely rare. An anaphylaxis pack which enables immediate access to epinephrine (adrenaline) 1 in 1000 injection and access to a telephone must always be readily available in case of an anaphylactic event following the administration of the vaccine. A PGD for adrenaline 1 in 1000 injection is not required as it is exempt from the prescription-only medicine requirement when administered for the purpose of saving a life in an emergency.
Records	In all cases, regardless of the setting where the vaccine is administered, vaccinators must ensure that records are kept in line with NMC Record Keeping Guidance. All records should be clear, legible and contemporaneous. Records should be signed and dated (or a password controlled immuniser's record on e-records). Documentation includes the Personal Held Child Record (PHCR – red book), other hand held records (e.g. maternity), GP records, computerised records and data collection for Child Health Information Services (CHIS), where applicable. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. The local CHIS team (Child Health Records Department) must be notified using the appropriate documentation/pathway when vaccine is administered to individuals under 19 years of age. The record should include: ▪ Assessment of the patient's need in relation to the intervention ▪ That valid informed consent was given ▪ Patient's name, address, date of birth and GP with whom the patient is registered ▪ Name of immuniser ▪ Name and brand of vaccine ▪ Dose, form and route of administration ▪ Quantity administered ▪ Anatomical site of administration ▪ Batch number and expiry date ▪ Date given ▪ Advice given to the patient/carer ▪ Advice given, including if excluded or declines immunisation ▪ For any contraindications/exclusions the course of action taken and the outcome ▪ Details of any adverse drug reactions and actions taken ▪ Record that the supply was made via PGD A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

	Medications given under a PGD should be appropriately READ coded in the patients clinical record. The READ codes to be used are: • SystmOne - XaQA7 • EMIS – 8BMN Clinical records must be kept in line with Records management code of practice for health and social care (DH 2016) Appendix 3 of the Code contains the detailed retention schedules.

7. Key references

Key references	**HepB vaccine** • Hepatitis B: guidance, data and analysis. Updated July 2017 https://www.gov.uk/government/collections/hepatitis-b-guidance-data-and-analysis • Hepatitis B: vaccine recommendations during supply constraints. August 2017 https://www.gov.uk/government/publications/hepatitis-b-vaccine-recommendations-during-supply-constraints • NHS public health functions agreement 2017-18, Service specification No.1 Neonatal hepatitis B immunisation programme. April 2017 https://www.england.nhs.uk/wp-content/uploads/2017/04/service-spec-01.pdf • Immunisation Against Infectious Disease: The Green Book Chapter 4 updated June 2012 Chapter 18 o born on or after 1 August 2017: updated June 2017; o born up to and including 31 July 2017: updated February 2016 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 (pre-filled syringe) http://www.medicines.org.uk/emc/medicine/24844 (vials) • Summary of Product Characteristic for HBvaxPRO® 5micrograms and 10micrograms. Sanofi Pasteur MSD Ltd. 05 June 2014. http://www.medicines.org.uk/emc/medicine/9850 http://www.medicines.org.uk/emc/medicine/9847 • Summary of Product Characteristic for HBvaxPRO® 5micrograms and 10micrograms. Sanofi Pasteur MSD Ltd. 05 June 2014. http://www.medicines.org.uk/emc/medicine/9850 http://www.medicines.org.uk/emc/medicine/9847 • Travel Health Pro Health Factsheet 'Hepatitis B'. May 2016 http://travelhealthpro.org.uk/factsheet/50/hepatitis-b **General** • 2017/18 Vaccination and immunisation. NHS Employers. May 2017 http://www.nhsemployers.org/your-workforce/primary-care-contacts/general-medical-services/vaccination-and-immunisation/2017-18-vaccinations-and-immunisations • British National Formulary (BNF) and British National Formulary for Children (BNF-C) https://www.medicinescomplete.com/mc/index.htm • 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 • Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336

	• National Minimum Standards for Immunisation Training (2005) https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published August 2013 updated Mar 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014. https://www.nice.org.uk/guidance/mpg2/resources • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

Individual Practitioner Authorisation

Organisations must complete an Individual Practitioner Authorisation sheet for each person planning to practice under this PGD. You do not need to return signed sheets to NHS England but you should retain copies as part of your organisation's internal governance arrangements. You may wish to retain a copy in the individual's personal file.

Practitioner

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PATIENT GROUP DIRECTIONS DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTISE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE AND PROFESSIONAL CODE.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct

Name (Print)	Designation	Signature	Date

Authorising Manager

I confirm that the practitioner named above who has signed the PGD has declared themselves suitably trained and competent and that I too have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so.

Designated Manager to give authorisation for the health care professional

Organisation:			
Name (Print)	**Designation**	**Signature**	**Date**

THIS AUTHORISATION SHEET SHOULD BE RETAINED TO SERVE AS A RECORD OF THOSE PRACTITIONERS AUTHORISED TO WORK UNDER THIS PGD.

APPENDIX A

Table 1: Current UK licensed HepB vaccine doses

Age	Vaccine	Dose	Volume
0–15 years*	Engerix B®**	10 micrograms	0.5ml
	HBvaxPRO®**	5 micrograms	0.5ml
16 years or over	Engerix B®	20* micrograms	1ml
	HBvaxPRO®	10 micrograms	1ml

*20 micrograms of Engerix B® may be given to children 11-15 years of age if using the two dose schedule.
**During supply shortages of paediatric hepatitis B containing vaccine, the full 1ml adult preparation of hepatitis B containing vaccine may be administered to infants (off-label) rather than delay or risk omitting HepB vaccination in individuals at high risk *(see Section: Additional Information).* The adult preparations may be used interchangeably with the paediatric products when vaccine becomes available *(for order of preference see Section: Additional Information*).

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/infected 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/infected mothers. *Dose from 2 months of age may be provided by multivalent vaccine, e.g. 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.
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 to 18 years of age *(see Section: Off-label use)* where it is important to provide rapid protection and to maximise compliance i.e. those who are at immediate risk and when very rapid immunisation is required e.g. PWID and those in prison) in accordance with Chapter 18 of The Green Book.
Booster (Engerix B®, HBvaxPro®)*: • Single dose administered 5 years after the primary course or, • for children born before 01/08/2017 to hepatitis B positive/infected mothers given with the pre-school boosters**	Use once to maintain immunity for those who continue to be at risk. ** *Children born to hepatitis B positive/infected mothers who have received five or more HepB doses, from either monovalent or multivalent vaccine (e.g. 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.*

**HBvaxPRO® and Engerix B® may be used interchangeably to complete the vaccine course.*

Scheduled HepB vaccine doses may be fulfilled by multivalent vaccine when appropriate.

This PGD does not cover the administration of multivalent vaccines.