Public Health England

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PATIENT GROUP DIRECTION (PGD)

Administration of Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed) to individuals who are 15 years of age or over and are on haemodialysis, a renal transplantation programme or have chronic renal failure that is likely to require haemodialysis or transplant.

This PGD is for the administration of Hepatitis B (rDNA) vaccine (adsorbed) (HepB vaccine) by currently registered nurses.

Reference no:	HepB Renal PGD
Version no:	v01.00
Valid from:	01 May 2017
Review date:	01 November 2018
Expiry date:	30 April 2019

Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended.

Operation of this PGD is the responsibility of commissioners and service providers.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

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 PHE PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

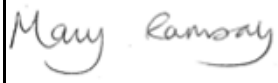
[1] This includes any relevant amendments to legislation (eg 2013 No235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	28/03/2017

1. PGD template development

This PGD template has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		25/04/2017
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		25/04/2017
Registered Nurse	David Green Nurse Consultant – Immunisations, PHE		25/04/2017

This PGD template has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by PHE Medicines Management Group and PHE Quality and Clinical Governance Steering Group.

Acknowledgements

Name	Designation
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Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Sue Mulvenna	Head of Pharmacy - NHS England South West
Graham Munslow	Clinical Screening and Immunisation Manager, NHS England / Public Health England Greater Manchester Health and Social Care partnership
Matthew Olley	Immunisation Manager, Public Health England / NHS England- London Region
Lisa Rees	Medicines Management Pharmacist, Bristol Clinical Commissioning Group
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East

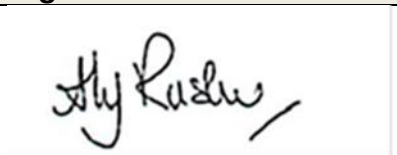
2. Organisational authorisations

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. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS ENGLAND MIDLANDS AND EAST (CENTRAL MIDLANDS) authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
General medical practices from which NHS England Midlands and East (Central Midlands) commissions immunisation services
Limitations to authorisation

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director, NHS England Midlands and East (Central Midlands)	**Dr Aly Rashid**		**22nd May 2017**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to

For Bedfordshire, Hertfordshire, Luton and Milton Keynes - england.immsqa@nhs.net - the (Central Midlands) South public health/screening and immunisation team

For Leicestershire, Lincolnshire and Northamptonshire – england.llimms@nhs.net - the (Central Midlands) North and Central public health/screening and immunisation team

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses currently registered with the Nursing and Midwifery Council (NMC)
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 • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics, 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 for Immunisation Training (2005) • 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 • must have access to the Patient Group Direction and associated online resources • should 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.**
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. Note: 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 specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals who are 15 years of age or over and are on haemodialysis, a renal transplantation programme or have chronic renal failure (CKD stage 4 or 5) that is likely to require haemodialysis or transplant in accordance with the recommendations given in Chapter 7 and Chapter 18 of Immunisation Against Infectious Disease: "The Green Book".
Criteria for inclusion	Individuals who are 15 years of age or over and are on haemodialysis, a renal transplantation programme or have chronic renal failure (CKD stage 4 or 5) that is likely to require haemodialysis or transplant.
Criteria for exclusion[2]	Individuals for whom no valid consent has been received. Individuals who: • are under 15 years of age • 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 • do not have a renal indication for HepB vaccination (see PHE HepB PGD) • are suffering from acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation)
Cautions including any relevant action to be taken	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.
Action to be taken if the patient is excluded	Individuals who are under 15 years of age who are on haemodialysis, or renal transplantation programmes, or with chronic renal failure (CKD stage 4 or 5) that is likely to require haemodialysis or transplant, should be referred for specialist advice on the appropriate vaccination schedule. A PSD is required as vaccination of these individuals is outside the remit of this PGD. Individuals who have had a confirmed anaphylactic reaction to a

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[2] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside the PGDs remit and another form of authorisation will be required

Action to be taken if the patient is excluded (continued)	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 (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 do not have a renal indication for HepB vaccination should be managed in accordance with PHE HepB PGD. 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 the patient or carer declines treatment	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. Document advice given and the decision reached. In a GP practice setting, inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength & formulation of drug	Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed)* (HepB) eg: • Engerix B® 20micrograms/1ml suspension for injection in pre-filled syringe or vial • Fendrix® 20 micrograms/0.5ml suspension for injection in pre-filled syringe* • HBvaxPRO® 40micrograms/1ml suspension for injection in a vial *the hepatitis B surface antigen in Fendrix® is adjuvanted by AS04C
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	Administration of Fendrix® by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in Chapter 4 and Chapter 18 of "The Green Book". Recommendations in the Green Book Chapter 18 allow for concomitant administration of HepB vaccine with other vaccines at a separate site when required. For Fendrix®, such administration would be off-label as, due to a lack of data, the SPC for Fendrix® advises an interval of 2 to 3 weeks be respected between the adminstration of Fendrix® and other vaccines. 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 deltoid region of the upper arm. 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 subcutaneous injection 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 (Fendrix®/ 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 Summary of Product Characteristics (SPC) provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk

Dose and frequency of administration

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

Table 1: Current UK licensed HepB vaccine doses for adolescents and adults with renal insufficiency including dialysis

Age	**Vaccine**	**Dose**	**Volume**
Patients with renal insufficiency and dialysis patients aged 16 years and over	Engerix B®	2 x 20 micrograms	2 x 1.0ml
Adult dialysis and pre-dialysis patients	HBvaxPRO®	40 micrograms	1.0ml
Patients with renal insufficiency aged 15 years and over	Fendrix®	20 micrograms	0.5ml

Table 2: Schedule for adolescents and adults with renal insufficiency including dialysis

Schedule	**Examples of when to use this schedule**
Engerix B® 20micrograms / 1.0ml: • 4 double doses (2 x 20 micrograms) at 0,1, 2 and 6 months after the first dose	Use for individuals from 16 years of age.
HBvaxPRO® 40micrograms / 1.0ml: • 3 doses at 0,1 and 6 months after the first dose	Use for individuals from 16 years of age.
Fendrix®: • 4 doses at 0,1, 2 and 6 months after the first dose	Use for individuals from 15 years of age.
Booster (Engerix B® 20micrograms / 1.0ml, HBvaxPRO® 40micrograms / 1.0ml or Fendrix®): • single dose administered if anti-HBs levels fall below 10mIU/ml in an individual who has previously responded to the vaccine (levels should be monitored annually) • single dose to haemodialysis patients travelling to highly endemic areas if they have not received a booster in the last 12 months	Individuals on haemodialysis from 15 years of age (Engerix B® or HBvaxPRO® from 16 years of age or Fendrix® from 15 years of age)

Duration of treatment

Dependent on vaccine schedule, see Dose and frequency of administration.

Quantity to be supplied / administered

Dose of 0.5ml to 2ml per an administration depending on the vaccine product used, see 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 protocol for ordering storage and handling of vaccines and Green Book Chapter 3).
Storage	Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.
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, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions[3]	Immunological response may be diminished in those receiving immunosuppressive treatment. May be given at the same time as other vaccines. A detailed list of drug interactions is available in the Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions[3]	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 Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
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.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
Patient advice / follow up treatment Continued over page	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

[3] Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

Patient advice / follow up treatment (continued)	to return for vaccination. Individuals/carers should be informed about the importance of completing a course of hepatitis B immunisation.
Special considerations / additional information	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 vaccinees (see Chapter 18 for more detail). **Testing for evidence of infection or immunity** 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. Refer to Chapter 18 for advice on response to vaccine and the use of additional doses. **Choice of HepB vaccine** The response to HepB vaccine among patients with renal failure is lower than among healthy adults. However, increased response rates have been reported in vaccines formulated for use in patients with chronic renal failure. Therefore, the vaccines formulated for use in patients with chronic renal insufficiency should be used for these individuals. **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.
Records Continued over page **Records**	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.

(continued)	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 Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway when vaccine is administered to individuals under 19 years of age. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	HepB vaccine • Immunisation Against Infectious Disease: The Green Book Chapter 4, last updated June 2012, Chapter 18, last updated 26 February 2016. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Engerix B®, GlaxoSmithKline. 24 November 2015. http://www.medicines.org.uk/emc/medicine/9283 http://www.medicines.org.uk/emc/medicine/24844 • Summary of Product Characteristic for HBvaxPRO® 40mcg. Sanofi Pasteur MSD Ltd. 05 June 2014. http://www.medicines.org.uk/emc/medicine/9848 • Summary of Product Characteristic for Fendrix®. GlaxoSmithKline. 24 November 2014. http://www.medicines.org.uk/emc/medicine/16906 **General** • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • British National Formulary (BNF) and British National Formulary for Children (BNF-C) www.BNF.org https://www.evidence.nhs.uk/formulary/bnf/current • 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. 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 • Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336 • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines • 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

7. Multiple practitioner authorisation sheet

HepB Renal PGD v01.00 Valid from: 01/05/2017 Expiry: 30/04/2019

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 of conduct.

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	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of _____ (**INSERT NAME OF ORGANISATION)** for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.