# NHS Grampian

NHS Grampian

Medicines Management Team
Pharmacy and Medicines Directorate
Westholme
Woodend Hospital
Queens Road
Aberdeen
AB15 6LS

Date: 12th of July 2022
Our Ref: FA/PGD/HepB/MGPG1031/July22
Enquiries to: MGPG
Extension: 56689
Direct Line: 01224 556689
Email: gram.mgpg@nhs.scot

Dear Colleagues

This letter authorises the extended use of the following North of Scotland (NoS) Patient Group Direction (PGD) until 1st October 2022:

**Patient Group Direction For The Administration Of Hepatitis B Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 1.2**

This PGD is currently under review following the release of the Public Health Scotland PGD template on June 30th. This letter provides permission to continue using the PGD to a new expiry date of 1st October 2022, and should be kept with the PGD records and brought to the attention of the individual healthcare professionals who operate under the PGD currently.

If you have any queries regarding this please do not hesitate to contact Frances Adamson the Clinical Lead for NoS PGD working.

Yours sincerely

**Lesley Coyle**
**Chair of North of Scotland PGD Group**

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

# Patient Group Direction For The Administration Of Hepatitis B Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

| | | |
|---|---|---|
| **Lead Author:**<br>Medicines Management Specialist Nurse NHS Grampian | **Consultation Group:**<br>See relevant page in the PGD | **Approver:**<br>NoS PGD Group<br><br>**Authorisation:**<br>NHS Grampian |
| **Signature:**<br>  | | **Signature:**<br>  |
| **NoS Identifier:**<br><br>NoS/PGD/HepB/ MGPG1031 | **Review Date:**<br><br>June 2021<br><br>**Expiry Date:**<br><br>June 2022 | **Date Approved:**<br><br>June 2019 |

**NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.**

**Uncontrolled when printed**

**Version 1.2 (Amended May 2021)**

## Revision History:

| | |
|---|---|
| **Reference and approval date of PGD that has been adapted/ superseded** | New PGD adapted from and supersedes NHSG/PGD/HepB/MGPG872 - Approved May 2017, NHSH 14_04_v8 - Approved May 2016, NHST Hepatitis B PGD - Approved September 2017. |

| **Date of change** | **Summary of Changes** | **Section heading** |
|---|---|---|
| February 2019 | Transferred to NoS PGD template at the time of 2 year review. NHSH, NHST, NHSO, NHSS and NHSWI added to PGD. | Throughout |
| February 2019 | Table added for schedules. | Frequency of dose/Duration of treatment |
| February 2019 | Statement added regarding off-label use of Engerix B®. | Legal status |
| February 2019 | Green Book table for hepatitis B prophylaxis for reported exposure incidents added as an Appendix. | Appendix 3 |
| April 2019 | Statement added regarding HepB vaccination as part of the 6:1 childhood vaccination for all babies. | Inclusion criteria |
| April 2019 | Term IDU replaced with PWIDs. | Inclusion criteria |
| April 2019 | Statement added regarding indication for foster carers in relation to NHSH. | Inclusion criteria |
| April 2019 | Statement added regarding exclusion applying in NHSH only. | Exclusion criteria |
| November 2019 | Removal of the reinforcing 5 year booster dose for healthcare professionals in-line with updated advice from Health Protection Scotland. N.B. Appendix 3 will be updated in the future once the Green Book Chapter 18 is updated. | Inclusion criteria |
| November 2019 | PGD updated to newest NoS template v4. | Throughout |
| May 2021 | Information in-line with the Green Book to allow nurses to give an additional booster dose following serology added. | Frequency of dose/Duration of treatment |

| | |
|---|---|
| **NOS Identifier:** | NoS/PGD/HepB/MGPG1031 v1.2 |
| **Keyword(s):** | PGD Patient Group Direction vaccine nurse pharmacist hepatitis b Fendrix Engerix B HBvaxPro |

**Policy Statement:** It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.
**Review date:** The review date for a PGD needs to be decided on a case-by-case basis in the interest of individual safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

| | | |
|---|---|---|
| Document: | Drafted: | February 2019 |
| | Completed: | April 2019 |
| | Approved: | June 2019 (published – July 2019) |
| | Amended: | November 2019, May 2021 |

**This document is also available in large print and other formats and languages, upon request. Please contact the appropriate NHS Board Communications Department:**

**NHS Grampian & NHS Orkney 01224 551116 or 01224 552245.**
**NHS Highland 01463 704722**
**NHS Shetland 01595 743310**
**NHS Tayside 01382 424138**
**NHS Western Isles coms.wi@nhs.net**

**N.B.** This PGD was impact assessed on 25/06/2019.

## Organisational Authorisations

**This PGD is not legally valid until it has had the relevant organisational authorisation.**
**PGD Developed/Reviewed by;**

| | |
|---|---|
| **Medical practitioner** | **Name:** Dr Daniel Chandler<br>**Health Board:** NHST<br>**Title:** Consultant in Public Health Medicine<br>**Contact email:** d.chandler@nhs.net<br>**Signature** ..... |
| **Senior representative of the professional group who will provide care under the direction.** | **Name:** Fiona Browning<br>**Health Board:** NHSG<br>**Title:** Health Protection Nurse Specialist<br>**Contact email:** fiona.browning@nhs.net<br>**Signature** ..... |
| **Lead author** | **Name:** Frances Adamson<br>**Health Board:** NHSG<br>**Title :** Medicines Management Specialist Nurse<br>**Contact email:** f.adamson@nhs.net<br>**Signature** ..... |
| **Pharmacist** | **Name:** Mary McFarlane<br>**Health Board:** NHSS<br>**Title :** Principal Pharmacist<br>**Contact email:** mary.mcfarlane@nhs.net<br>**Signature** ..... |

**Approved for use within NoS Boards by;**

| North of Scotland (NoS) PGD Group | Signature | Date Signed |
|---|---|---|
| Lesley Thomson |  | June 2019 |

**Authorised and executively signed for use within NoS Boards by;**

| NHS Grampian Chief Executive | Signature | Date Signed |
|---|---|---|
| Professor Amanda Croft |  | July 2019 |

**Management and Monitoring of Patient Group Direction**

**PGD Consultative Group**

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

| Name: | Title: |
|---|---|
| Frances Adamson | **Lead Author:** Medicines Management Specialist Nurse NHSG |
| Mary McFarlane | **Pharmacist:** Principal Pharmacist NHSS |
| Dr Daniel Chandler | **Medical Practitioner:** Consultant in Public Health Medicine NHST |
| Fiona Browning | **Senior Representative:** Health Protection Nurse Specialist NHSG |
| Dr Ambreen Butt | Consultant in Sexual Health and HIV NHSG |
| Dr Carol Close | Speciality Doctor OHS NHSG |
| Lorraine McKee | Health Protection Nurse Specialist NHSH |
| Tina McMichael | Advanced Nurse Specialist (Health Protection) NHST |
| Rhiannon Sharp | Lead Nurse Travel Clinic GO Health NHSG |

# Patient Group Direction For The Administration Of Hepatitis B Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

## Clinical indication to which this PGD applies

| | |
|---|---|
| **Definition of situation/Condition** | This Patient Group Direction (PGD) will authorise approved healthcare professionals to administer Hepatitis B (HepB) vaccine for active immunisation of non-immune individuals at high risk of contracting hepatitis B. This PGD is designed to facilitate immunisation across a range of suitable environments, to encourage access by all eligible individuals to take up the vaccine.<br><br>This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book Chapter 18, TRAVAX, NaTHNaC, the individual Summary of Product Characteristics (SmPC) and local policies and procedures as applicable. |
| **Inclusion criteria** | **N.B.** The following criteria apply across all NoS Health Boards with the exception of immunisation for the purposes of **travel** or **occupational exposure**; these **do not apply** in NHST or NHSO where a private prescription will be required for these indications.<br><br>**Pre-exposure immunisation is recommended for the following groups:**<br><br>• People Who Inject Drugs (PWIDs) their sexual partners, and household contacts including their children and those who are likely to progress to injecting<br>• Individuals who change sexual partners frequently, particularly men who have sex with men (MSM) and female commercial sex workers<br>• Close family/household/sexual contacts of a case or individual with chronic HepB infection<br>• Individuals with haemophilia; those receiving regular blood transfusions or blood products and their carers<br>• Individuals with chronic renal failure who are receiving haemodialysis or on transplant programmes, or are anticipated to require these interventions<br>• Individuals with chronic liver disease, including those with chronic hepatitis C infection<br>• Previous and current inmates of custodial institutions in the UK, including those on remand<br>• Families adopting children from countries with a high/intermediate prevalence of HepB. |

| | |
|---|---|
| | • Individuals travelling to or going to reside in areas of high or intermediate prevalence including;<br>  o those who plan to remain in areas of high or intermediate prevalence for lengthy periods<br>  o children and others who may require medical care while travelling to visit families or relatives in high or moderate-endemicity countries<br>  o people with chronic medical conditions who may require hospitalisation while overseas, e.g. dialysis<br>  o those travelling for medical care<br><br>**N.B.** All babies are now offered HepB vaccination as part of the 6:1 childhood vaccination.<br><br>**Occupational Exposure**<br><br>The following groups are also encouraged to be vaccinated but it is their employers' responsibility to arrange vaccination, as there may be a cost associated with this;<br><br>• Healthcare workers (including students and trainees) at occupational risk, or laboratory workers who have direct contact with patient's blood or blood-stained body fluids or patient's tissues working directly with the virus, those in contact with raw sewage<br>• Staff of large institutions for those with learning disabilities<br>• Individuals who work with primates<br>• Members of emergency services following risk assessment<br>• Staff of custodial institutions<br>• Foster carers and their families (**N.B.** This does not apply in NHSH where a private prescription is required for this indication).<br><br>**Post-exposure immunisation is recommended for the following groups:**<br><br>• Babies born to mothers who are chronic carriers of hepatitis B virus or who have had acute hepatitis B during pregnancy.<br>• Individuals who may have been accidentally exposed to infected blood/body fluids.<br>• Anyone living in a household with an individual who is known to have HepB infection. |

| | |
|---|---|
| | **Reinforcing immunisation (Booster Dose)**<br><br>Those who have receive post-exposure prophylaxis with a zero, one and two months accelerated schedule, do not require a further dose at 12 months unless they remain at continued high risk. Thereafter, these individuals do not require a reinforcing dose of HepB containing vaccine, except in the following categories:<br>• Individuals with renal failure<br>• At the time of a subsequent significant exposure (See Appendix 3).<br><br>**N.B.** Additionally any groups of patients as identified by the Health Protection Team should be immunised pre or post-exposure.<br><br>Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy. |
| **Exclusion criteria** | **N.B.** There are very few individuals who cannot receive HepB containing vaccines. When there is doubt, appropriate advice should be sought from the relevant specialist consultant, the local screening and immunisation team or local Health Protection Team rather than withholding vaccine.<br><br>The vaccine should not be administered in the following circumstances:<br>• Individuals with current febrile illness<br>• Individuals who have had an anaphylactic reaction to previous dose of the vaccine or to any of its excipients<br>• Person known to be HepB surface antigen positive<br>• No valid consent.<br><br>**The following exclusion applies within NHS Highland only;**<br><br>• Individual being immunised for travel purpose – GP10 prescription required. |
| **Precautions and special warnings** | Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered, in order to prevent confusion of the symptoms of the illness with any adverse effects of the vaccine. |

| | |
|---|---|
| | Individuals with a Bleeding Disorder - An individual risk assessment should be undertaken prior to vaccination. As with any intramuscular (IM) vaccination, the injection should be given with caution to individuals with thrombocytopenia or any coagulation disorder as bleeding may occur following an intramuscular administration to these subjects. Therefore, individuals with known bleeding disorders or on anticoagulant therapy should receive the vaccine by deep subcutaneous injection route to reduce the risk of bleeding. Individuals should be informed of the risk of developing haematoma and what to do if this occurs. |
| **Action if excluded from treatment** | Medical advice must be sought – refer to relevant medical practitioner. If clarification is required about an individual meeting the exclusion criteria advice can be sought from the local Health Protection Team.<br><br>The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records.<br><br>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged.<br><br>Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records, and inform the appropriate clinician, e.g. GP/District Nurse/Health Visitor/Family Nurse/Midwife/Paediatrician. |
| **Action if treatment is declined** | Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material, e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached.<br><br>Inform/refer to the relevant medical practitioner if individual/person with parental responsibility declines treatment.<br><br>Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records. |

## Description of vaccine available under the PGD

<table>
<tr><td>Name form and strength of medicine</td><td>Hepatitis B vaccine is available as Engerix B®, HBvaxPRO® and Fendrix®.<br><br>Engerix B® is presented as a suspension for injection containing 20 micrograms/mL hepatitis B surface antigen. It is available in 0.5mL or 1mL pre-filled syringes or vials.<br><br>Fendrix® is available as a 0.5mL pre-filled syringe containing 40 micrograms/mL hepatitis B surface antigen.<br><br>HBvaxPRO®5mcg contains 5 micrograms/0.5mL hepatitis B surface antigen and is available as a 0.5mL pre-filled syringe.<br><br>HBvaxPRO®10mcg contains 10 micrograms/mL hepatitis B surface antigen and is available as a 1mL pre-filled syringe.<br><br>HBvaxPRO®40mcg contains 40 micrograms/mL hepatitis B surface antigen and is available as a 1mL vial.</td></tr>
<tr><td>Legal status</td><td>Hepatitis B vaccine is a Prescription-only Medicine (PoM).<br><br>N.B. 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 where it is important to provide rapid protection and to maximise compliance (e.g. PWIDs and those in prison) in accordance with Chapter 18 of “The Green Book”. The person with parental responsibility should be informed prior to the administration that the use is off-label.</td></tr>
<tr><td>Dosage/Maximum total dose</td><td>
<table>
<tr><th>Vaccine product</th><th>Ages and group</th><th>Dose</th><th>Volume</th></tr>
<tr><td>Engerix B®</td><td>0 - 15 years*</td><td>10 micrograms</td><td>0.5mL</td></tr>
<tr><td>Engerix B®</td><td>16 years or over</td><td>20 micrograms</td><td>1.0mL</td></tr>
<tr><td>Fendrix®</td><td>Individuals with renal insufficiency aged 15 years and over</td><td>20 micrograms</td><td>0.5mL</td></tr>
<tr><td>HBvaxPRO®5mcg</td><td>0 - 15 years</td><td>5 micrograms</td><td>0.5mL</td></tr>
<tr><td>HBvaxPRO®10mcg</td><td>16 years or over</td><td>10 micrograms</td><td>1.0mL</td></tr>
<tr><td>HBvaxPRO®40mcg</td><td>Adult dialysis and pre-dialysis individuals</td><td>40 micrograms</td><td>1.0mL</td></tr>
</table>
* 20micrograms of Engerix B® may be given to children 11 - 15 years of age if using the two-dose schedule (see below).
</td></tr>
</table>

**Frequency of dose/Duration of treatment**

**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*:**<br>• 3 doses at 0, 1, and 2 months<br>• further dose 12 months after the first dose for babies born to hepatitis B positive mothers and individuals at continued risk e.g. healthcare workers | Used for individuals of all ages for pre and post-exposure prophylaxis.<br>This is the preferred schedule for babies born to hepatitis B positive mothers. **N.B.** dose from 2 months of age is 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. |
| **Standard schedule*:**<br>• 3 doses at 0, 1, and 6 months | This regime is suitable in occupational health setting where compliance has been shown to be high. Otherwise; 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:**<br>• 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 schedule (Engerix B® only):**<br>• 3 doses at 0, 7 days and 21 days<br>• 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, e.g. IDUs, sexual exposure and prisoners. This schedule is also advised for travellers who will be travelling to areas of high endemicity. |

| Schedule | Examples of when to use this schedule |
|---|---|
| **Booster Dose (Engerix B®, HBvaxPro®)*:**<br>• 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.<br>**Children born to hepatitis B 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. See Appendix 3 for further information regarding booster doses post-exposure. |

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

**Predialysis/Dialysis**

Fendrix® - initial dose repeated after 1, 2 and 6 months (preferred licensed vaccine for use in renal failure).

Engerix B® - initial dose repeated after 1, 2 and 6 months.

HBvaxPRO - initial dose repeated after 1 and 6 months.

**N.B.** Scheduled HepB vaccine doses may be fulfilled by multivalent vaccine when appropriate. This PGD does not cover the administration of multivalent vaccines.

**Response to vaccine and the use of additional doses**
Those at occupational risk and individuals with HIV – check antibody levels 1 to 2 months after completion of the primary course. Responders with anti-HBs levels greater than or equal to 100mIU/mL do not require any further primary doses.

Responders with anti-HBs levels of 10 to 100mIU/mL should receive one additional dose of vaccine at that time.

For those at occupational risk with antibody levels <10mIU/mL repeat the vaccine course and re-test after 1 to 2 months. Seek advice if antibody levels remain <10mIU/mL.

| | |
|---|---|
| **Maximum or minimum treatment period** | See Frequency of dose/Duration of treatment section above. |
| **Route/Method of administration** | Administration of the vaccine should be given by intramuscular injection (IM). The deltoid muscle is the preferred site for injection in adults and older children. For children under one year of age the anterolateral thigh is the preferred site for injection.<br><br>This vaccine **should not be given** by the intravenous or intradermal routes under any circumstances.<br><br>Individuals with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding. The needle should be inserted at a 45° angle to the skin and the skin should be bunched, not stretched. Pressure (no rubbing) should be applied to the injection site for at least 5 minutes following vaccination.<br><br>When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to the HepB. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records.<br><br>Shake before injection to obtain a slightly opaque white suspension. The vaccine should be visually inspected before administration for any foreign particulate matter. |
| **Quantity to be administered** | See Dosage/Maximum total dose and Frequency of dose/Duration of treatment sections above. |
| **Storage requirements** | Vaccine will be stored in a temperature controlled refrigerator between +2°C to +8°C. Refrigerators should have maximum and minimum temperatures recorded daily.<br><br>Store in original packaging in order to protect from light.<br><br>Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed. |

| | |
|---|---|
| **Follow-up (if applicable)** | Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice. |
| **Advice (Verbal)** | Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions.<br><br>If serious adverse or persistent effects occur, the individual/person with parental responsibility should be advised to contact their GP/Accident and Emergency Department/NHS24.<br><br>When administration is postponed advise the individual/person with parental responsibility when to return for vaccination.<br>If appropriate, advise the individual/person with parental responsibility when subsequent doses are due and if any follow up is required. |
| **Advice (Written)** | The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.<br><br>Provide/refer where appropriate to national leaflet Hepatitis B immunisation for babies born to mothers with hepatitis B.<br><br>More information regarding this vaccine can be found at: https://www.nhsinform.scot/healthy-living/immunisation |
| **Identifying and managing possible adverse reactions** | 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. The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site.<br><br>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.<br><br>As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. |

| | |
|---|---|
| | **This list is not exhaustive. Please also refer to current BNFC/BNF and manufacturers SmPC for details of all potential adverse reactions.**<br><br>**BNFC/BNF**:<br>https://about.medicinescomplete.com/<br><br>**SmPC/PIL/Risk Minimisation Material:**<br>https://www.medicines.org.uk/emc/<br>http://www.mhra.gov.uk/spc-pil/index.htm<br>https://www.medicines.org.uk/emc/rmm-directory<br><br>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.<br><br>Report any severe reactions using the MHRA using the Yellow Card System. https://yellowcard.mhra.gov.uk/ |
| **Facilities and supplies required** | The following are to be available at sites where the vaccine is to be administered:<br>• Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit)<br>• An acceptable level of privacy to respect individual's right to confidentiality and safety<br>• Basic airway resuscitation equipment (e.g. pocket mask, bag valve mask, supraglottic airway)<br>• Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection<br>• Access to a working telephone<br>• Another competent adult, who can summon urgent emergency support if required should ideally be present<br>• Access to medical support (this may be via the telephone)<br>• Approved equipment for the disposal of used materials<br>• Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel<br>• A copy of this PGD in print or electronically. |

## Characteristics of staff authorised to administer medicine under PGD

| | |
|---|---|
| **Professional qualifications** | Registered Nurses and Midwives as recognised by the Nursing and Midwifery Council (NMC). Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC). |
| **Specialist competencies** | **Approved by the organisation as:**<br>• Competent to assess the individual's/person with parental responsibility capacity to understand the nature and purpose of vaccination in order to give or refuse consent |

| | |
|---|---|
| | • Competent to undertake administration of the vaccine and discuss issues related to vaccination<br>• Competent in the handling and storage of vaccines, and management of the "cold chain" in accordance with relevant local policy and guidance<br>• Competent to work under this PGD. |
| **Ongoing training and competency** | **All professionals working under this PGD must:**<br>• Have undertaken PGD training as required/set out by each individual Health Board<br>• Have undertaken immunisation training where available<br>• Have attended basic life support training which is required to be updated annually<br>• Have undertaken NHS e-anaphylaxis training or equivalent (including annual updates) which covers all aspects of the identification and management of anaphylaxis<br>• Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct<br>• Have knowledge and familiarity of the following;<br>o Current edition of the Green Book<br>o SmPC for the vaccine to be administered in accordance with this PGD<br>o Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board<br>o Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s). |
| **Responsibilities of professional manager(s)** | **Professional manager(s) will be responsible for;**<br><br>Ensuring that the current PGD is available to all staff providing care under this direction.<br><br>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.<br><br>Maintain up to date record of all staff authorised to administer the vaccine specified in this direction. |

## Documentation

| | |
|---|---|
| **Authorisation of administration** | Nurses and Midwives working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the vaccine specified in this PGD by their Professional Line Manager/Consultant/Practice GPs. |

| | |
|---|---|
| | Pharmacists working within **NHS Grampian only** can be authorised to administer the vaccine specified in this PGD by their Director of Pharmacy.<br><br>All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board. |
| **Record of administration** | An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:<br>• Date and time of vaccine administration<br>• Individuals name and CHI<br>• Exclusion criteria, record why the vaccine was not administered, if applicable<br>• Record that valid consent to treatment under this PGD was obtained<br>• The name, brand, dose, form, batch number, expiry date, route/site of the vaccination administered<br>• Advice given, including advice given if excluded or declined treatment under this PGD<br>• Signature and name in capital letters of the healthcare professional who administered the vaccine<br>• Where childhood immunisations are given information of the administration must be provided to the GP Practice and Practitioner Services Division (PSD) for inclusion on the Scottish Immunisation Recall System (SIRS)<br>• Record of any adverse effects (advise individuals GP/relevant medical practitioner).<br><br>Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate.<br>• Consent forms<br>• Child Health Information Services if appropriate<br>• NaSH – Sexual Health Electronic Patient Record<br>• BadgerNet – Digital Maternity Notes<br>• Hand–held records such as red book if appropriate<br>• Individual's GP records if appropriate<br>• Secondary Care Medical Notes<br>• Occupational health systems<br>• Individual service specific systems. |

<table>
<tr><td>Audit</td><td>All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.</td></tr>
<tr><td>References</td><td>British National Formulary for Children and the British National Formulary https://about.medicinescomplete.com/ accessed 12/02/19.<br><br>Electronic Medicines Compendium - http://www.medicines.org.uk<br><br>
<table>
<tr><th>Vaccine</th><th>Date of Revision</th><th>Date Accessed</th></tr>
<tr><td>Engerix B®</td><td>24/04/17</td><td>12/02/19</td></tr>
<tr><td>Fendrix®</td><td>02/11/18</td><td>12/02/19</td></tr>
<tr><td>HBvaxPRO®5mcg</td><td>01/03/17</td><td>12/02/19</td></tr>
<tr><td>HBvaxPRO®10mcg</td><td>01/03/17</td><td>12/02/19</td></tr>
<tr><td>HBvaxPRO®40mcg</td><td>01/03/17</td><td>12/02/19</td></tr>
</table>
<br>Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book<br><br>American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.</td></tr>
</table>

**Appendix 1**

## Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

**I:** _____ (Insert name)

**Working within:** _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

## Patient Group Direction For The Administration Of Hepatitis B Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

**Signed:** _____

**Print Name:** _____

**Date:** _____

**Profession:** _____

**Professional Registration number/PIN** _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

**Appendix 2**

## Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

| |
|---|
| **The Lead manager/Professional** of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated. |
| **The Senior Nurse/Professional** who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons. |
| **The Healthcare Professional** that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct. |
| **Patient Group Direction For The Administration Of Hepatitis B Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles** |
| **Local clinical area(s) where the listed healthcare professionals will operate under this PGD:** |

| Name of Healthcare Professional | Signature | Date | Name of Manager | Signature | Date |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

| Patient Group Direction For The Administration Of Hepatitis B Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles | | | | | |
|---|---|---|---|---|---|
| **Name of Healthcare Professional** | **Signature** | **Date** | **Name of Manager** | **Signature** | **Date** |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**Appendix 3**

| | Significant exposure | | | Non-significant exposure | |
|---|---|---|---|---|---|
| **HBV status of person prior to exposure** | **HBsAg positive source** | **Unknown source** | **HBsAg negative source** | **Continued risk** | **No further risk** |
| Unvaccinated | Accelerated course of HepB vaccine plus HBIG with first dose | Accelerated course of HepB vaccine | Consider course of HepB vaccine | Initiate course of HepB vaccine | No HBV prophylaxis Reassure |
| Partially vaccinated | One dose of HepB vaccine and finish course | One dose of HepB vaccine and finish course | Complete course of HepB vaccine | Complete course of HepB vaccine | Complete course of HepB vaccine |
| Fully vaccinated with primary course | Booster dose of HepB vaccine if last dose ≥ 1year ago | Consider booster dose of HepB vaccine if last dose ≥ 1year ago | No HBV prophylaxis. Reassure | No HBV prophylaxis Reassure | No HBV prophylaxis Reassure |
| Known non-responder to HepB vaccine (anti-HBs < 10mIU/ml 1-2 months post-immunisation) | HBIG<br>Booster dose of HepB vaccine<br>A second dose of HBIG should be given at one month | HBIG<br>Consider booster dose of HepB vaccine<br>A second dose of HBIG should be given at one month | No HBIG<br>Consider booster dose of HepB vaccine | No HBIG<br>Consider booster dose of HepB vaccine | No HBV prophylaxis Reassure |

Green book Chapter 18 Table 18.7 Hepatitis B prophylaxis for reported exposure incidents.