



**Patient Group Direction For The Administration Of Combined Inactivated Hepatitis A and Hepatitis B Vaccine For Non-Travel Indications By Approved Healthcare Professionals Nurses And Pharmacists Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles**

<p><b>Lead Author:</b> Adapted from PHS National PGD by the Medicines Management Specialist Nurse NHSG</p>	<p><b>Consultation Group:</b> See relevant page in the PGD</p>	<p><b>Approver:</b> NoS PGD Group</p> <p><b>Authorisation:</b> NHS Grampian</p>
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<p><b>Signature:</b> </p>		<p><b>Signature:</b> </p>
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<p><b>NoS Identifier:</b> NoS/PGD/HepAB/MGPG1340</p>	<p><b>Review Date:</b> December 2024</p> <p><b>Expiry Date:</b> December 2025</p>	<p><b>Date Approved:</b> December 2022</p>
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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 3

**Revision History:**

<b>Reference and approval date of PGD that has been adapted and/or superseded</b>	PGD adapted from PHS national template and supersedes NoS/PGD/hepAB/MGPG1177, Version 2.1	
<b>Date of change</b>	<b>Summary of Changes</b>	<b>Section heading</b>
July 2022	PGD adapted from PHS national template and supersedes previous NoS HepA&B PGD.	
November 2022	Removal of those working with raw sewage.	Inclusion criteria
November 2022	Removal of chronic hepatitis B as an inclusion.	Inclusion criteria

**NoS Identifier:** NoS/PGD/HepAB/MGPG1340  
**Keyword(s):** PGD Patient Group Direction hepatitis A hepatitis B combined vaccine

**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 safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

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                           Amended & re-  
                           authorised:


## Organisational Authorisations

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


PGD Developed/Reviewed by;

<p><b>Medical practitioner</b></p>	<p><b>Name:</b> Dr William Moore  <b>Health Board:</b> NHSG  <b>Title:</b> Consultant Public Health Medicine  <b>Signature:</b> ..... <i>William Moore</i> .....  <b>Date Signed:</b> 16/11/2022</p>
<p><b>Senior representative of the professional group who will provide care under the direction.</b></p>	<p><b>Name:</b> Lynda Davidson  <b>Health Board:</b> NHSH  <b>Title:</b> Health Protection Nurse Specialist  <b>Contact email:</b> <a href="mailto:lynda.davidson@nhs.scot">lynda.davidson@nhs.scot</a>  <b>Signature:</b> ..... <i>Lynda Davidson</i> .....  <b>Date Signed:</b> 08/12/2022</p>
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**Approved for use within NoS Boards by;**

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		14/12/2022

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

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		30/12/2022

**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:**

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**Clinical indication to which this PGD applies**

<p><b>Definition of situation/Condition</b></p>	<p>This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer combined inactivated hepatitis A and hepatitis B vaccine to individuals for active immunisation against both hepatitis A and hepatitis B.</p> <p>This PGD should be used in conjunction with the recommendations in the current British National Formulary (<a href="#">BNF</a>), British National Formulary for Children (<a href="#">BNFC</a>), <a href="#">The Green Book</a> and the individual Summary of Product Characteristics (<a href="#">SmPC</a>).</p>
<p><b>Inclusion criteria</b></p>	<p>Individuals over 1 year of age requiring hepatitis A and hepatitis B pre-exposure prophylaxis including individuals who:</p> <ul style="list-style-type: none"> <li>• Have chronic liver disease (including alcoholic cirrhosis, chronic hepatitis C, autoimmune hepatitis, primary biliary cirrhosis).</li> <li>• Have haemophilia or receive regular blood products and carers responsible for administration of these products.</li> <li>• Change sexual partners frequently, are men who have sex with men (MSM) or commercial sex workers.</li> <li>• Are people who inject drugs (PWID) or those who are likely to progress to injecting, their sexual partners, and household contacts, including children.</li> <li>• Are rough sleepers or live in hostel accommodation.</li> <li>• Are members of a family adopting children from countries with a high or intermediate prevalence of hepatitis A and B.</li> <li>• 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 percutaneous exposure (such as biting or being bitten) on a regular basis.</li> <li>• Are healthcare workers (including students and trainees) at occupational risk.</li> <li>• Are laboratory workers who have direct contact with patient's blood or blood-stained body fluids or patient's tissues working directly with the virus,</li> <li>• Are staff of residential and other accommodation for those with learning difficulties.</li> </ul>

	<ul style="list-style-type: none"> <li>• Are individuals who work with primates.</li> <li>• Are staff of custodial institutions.</li> </ul> <p>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.</p>
<p><b>Exclusion criteria</b></p>	<p>Individuals who:</p> <ul style="list-style-type: none"> <li>• Are under 1 year of age.</li> <li>• Have had a confirmed anaphylactic reaction to a previous dose of any hepatitis A or hepatitis B vaccine or to any components of the vaccines, these may include neomycin (refer to relevant SmPC.)</li> <li>• Have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free.</li> <li>• Are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).</li> </ul> <p>Individuals for whom no valid consent has been received.</p>
<p><b>Precautions and special warnings</b></p>	<p>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.</p> <p>The Green Book advises there are very few individuals who cannot receive hepatitis A and hepatitis B containing vaccines. When there is doubt, appropriate advice should be sought from the lead clinician rather than withholding the vaccine.</p> <p>Individuals who have previously commenced a primary course of monovalent hepatitis A or hepatitis B vaccine should ideally continue the course with monovalent vaccines.</p> <p>Individuals who are immunosuppressed may not make a full antibody response.</p> <p>The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.</p>

<p><b>Action if excluded from treatment</b></p>	<p>Medical advice must be sought – refer to relevant medical practitioner for advice on the vaccine and circumstances under which it could be given using a patient specific direction.</p> <p>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.</p> <p>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.</p> <p>Individuals who have had a confirmed anaphylactic reaction to a previous dose of a hepatitis A or B containing vaccine or any components of the vaccines should be referred to a clinician for specialist advice and appropriate management.</p> <p>Advise individuals of preventative measures to reduce exposure to hepatitis A (such as careful attention to food and water hygiene and scrupulous hand washing) and preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids).</p> <p>Document the reason for exclusion under the PGD and any action taken in the individual’s appropriate clinical records.</p>
<p><b>Action if treatment is declined</b></p>	<p>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 <a href="#">here</a>. Document advice given and decision reached.</p> <p>Advise individuals of preventative measures to reduce exposure to hepatitis A (such as careful attention to food and water hygiene and scrupulous hand washing) and preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids).</p> <p>Inform/refer to the relevant medical practitioner if individual/parent/carer declines treatment.</p> <p>Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.</p>

**Description of vaccine available under the PGD**

<b>Name form and strength of vaccine</b>	<p>Hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (HepA/B) vaccine (adsorbed), as either:</p> <ul style="list-style-type: none"> <li>• Twinrix® Adult, suspension for injection in a pre-filled syringe or vial, hepatitis A virus (inactivated) 720 ELISA units and hepatitis B surface antigen 20micrograms.</li> <li>• Twinrix® Paediatric, suspension for injection in a pre-filled syringe or vial, hepatitis A virus (inactivated) 360 ELISA units and hepatitis B surface antigen 10micrograms.</li> <li>• Ambirix®, suspension for injection in a pre-filled syringe, hepatitis A virus (inactivated) 720 ELISA units and hepatitis B surface antigen 20micrograms.</li> </ul> <p><b>Note:</b> An appropriate vaccine product should be selected for the patient see dose and frequency section.</p>
<b>Legal status</b>	Hepatitis A and B Vaccines are Prescription-only Medicines (POM).
<b>Is the use out with the SmPC?</b>	<p>The Twinrix® Adult schedule given at 0, 7 and 21 days is licensed for adults (that is those from 18 years of age) but may be used off-label in those from 16 to 18 years of age where it is important to provide rapid protection and to maximise compliance (this includes PWID) in accordance with <a href="#">Chapter 18</a> of The Green Book. The individual or the person with parental responsibility should be informed prior to the administration that the use is off-label.</p> <p>Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.</p>
<b>Dosage/Maximum total dose</b>	Dependent on product, see Frequency of dose/Duration of treatment section below.
<b>Frequency of dose/Duration of treatment</b>	Current UK licensed hepatitis A and B vaccines contain different concentrations of antigen (see table below).



Vaccine	Age (licenced use)	Dose HepA	Dose HepB	Volume
Twinrix® Adult	16 years or over	720 ELISA units	20micrograms	1.0mL
Twinrix® Paediatric	One to 15 years	360 ELISA units	10micrograms	0.5mL
Ambirix®	One to 15 years	720 ELISA units	20micrograms	1.0mL

**Licensed dose to provide hepatitis A and B protection:**

- **Twinrix® Adult:** 1mL administered at 0, 1 and 6 months.

Where insufficient time is available to allow the standard 0, 1, 6 month schedule to be completed, a schedule of three intramuscular injections given at 0, 7 and 21 days may be used. When this schedule is applied, a fourth dose is recommended 12 months after the third dose.

- **Twinrix® Paediatric:** 0.5mL administered at 0, 1 and 6 months
- **Ambirix®:** 1mL administered at 0 and 6-12 months

**Reinforcing Immunisation:**

**Hepatitis A**

Until further evidence is available on persistence of protective immunity, a further booster at 25 years is indicated for those at ongoing risk.

**Hepatitis B**

Immunocompetent individuals that have received a complete primary course of hepatitis B immunisation, including children vaccinated according to the routine childhood schedule, do not require a reinforcing dose of hepatitis B containing vaccine, with the exception of:

- Occupational indications.
- Renal failure.
- After confirmed significant exposure to hepatitis.

Those at occupational risk of hep B should have antiHB's checked one to two months after. Depending on antibody

	<p>levels further doses may be indicated. Please refer to Chapter 18 page 18 of Green Book or hep B PGD for further guidance.</p> <p><b>Note:</b> If rapid protection against hepatitis A only is required for adults, for example following exposure or during outbreaks, then a single dose of monovalent vaccine is recommended (see Hepatitis A PGD).</p>
<b>Maximum or minimum treatment period</b>	As above in Frequency of dose/Duration of treatment section.
<b>Route/Method of administration</b>	<p>Administer by intramuscular injection.</p> <p>The preferred site is the deltoid region of the upper arm or the anterolateral area of the thigh muscle in small children.</p> <p>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the Green Book <a href="#">Chapter 4</a>.</p> <p>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.</p> <p>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 hepatitis A and B vaccine. 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.</p>
<b>Quantity to be administered</b>	See Frequency of dose/Duration of treatment section.
<b>Storage requirements</b>	<p>Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily.</p> <p>Store in original packaging in order to protect from light.</p> <p>Do not freeze.</p> <p>Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed.</p>

	<p>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.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal.</p>
<p><b>Additional Information</b></p>	<p>Immunological response may be diminished in those receiving immunosuppressive treatment.</p> <p>Hepatitis B vaccine may be given to HIV-infected individuals and should be offered to those at risk, since infection acquired by immunosuppressed, HIV- positive patients can result in higher rates of chronic infection. Response rates are usually lower depending upon the degree of immunosuppression. Increasing the number of doses or using a higher antigen content dose may improve the anti-HBs response in HIV-infected individuals. Further guidance is provided by the <a href="#">Royal College of Paediatrics and Child Health</a> the British HIV Association (BHIVA) immunisation guidelines for HIV-infected adults (BHIVA, 2015) and the <a href="#">Children’s HIV Association (CHIVA) immunisation guidelines</a>. There should be no delay in offering vaccination to individuals in whom HIV status is not known.</p> <p>There is no evidence of risk from vaccinating pregnant women, or those who are breast-feeding, with inactivated virus or bacterial vaccines or toxoids. Vaccination should be considered when the risk of infection is high and benefits are considered to outweigh the risks.</p>
<p><b>Follow-up (if applicable)</b></p>	<p>Following immunisation patients should remain under observation in line with individual NHS Board policy.</p> <p>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.</p>
<p><b>Advice (Verbal)</b></p>	<ul style="list-style-type: none"> <li>• Advise individual/parent/carer what to expect and of the possible side effects and their management.</li> <li>• The individual/parent/carer should be advised to seek medical advice in the event of a severe adverse reaction.</li> <li>• Individual/parents/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <a href="#">Yellow Card reporting scheme</a>.</li> <li>• Advise individuals of preventative measures to reduce exposure to hepatitis A (such as careful attention to food</li> </ul>

	<p>and water hygiene and scrupulous hand washing) and preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids).</p> <p>When administration is postponed advise the individual/parent/carer when to return for vaccination.</p> <p>If appropriate, advise when subsequent doses are due and if any follow up is required.</p>
<p><b>Advice (Written)</b></p>	<p>The PIL contained in the medicine(s) should be made available to the individual/parent/carer. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.</p> <p>More information regarding this vaccine can be found at: <a href="https://www.nhsinform.scot/healthy-living/immunisation">https://www.nhsinform.scot/healthy-living/immunisation</a></p>
<p><b>Identifying and managing possible adverse reactions</b></p>	<p>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.</p> <p>Adverse reactions to hepatitis vaccines are usually mild and confined to the first few days after immunisation. 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.</p> <p>Other commonly reported reactions include other injection site reactions (haematoma, pruritus, bruising), general symptoms such as fever, malaise, fatigue, irritability, drowsiness, headache, and gastrointestinal symptoms including nausea, diarrhoea and loss of appetite.</p> <p>As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.</p> <p><b>This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.</b></p> <p><b>BNF/BNFC:</b>  <a href="#">BNF British National Formulary - NICE</a>  <a href="#">BNF for Children British National Formulary - NICE</a></p>

	<p><b>SmPC/PIL/Risk Minimisation Material:</b>  <a href="#">Home - electronic medicines compendium (emc)</a>  <a href="#">MHRA Products   Home</a>  <a href="#">RMM Directory - (emc)</a></p> <p>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.</p> <p>Document in accordance with locally agreed procedures in the individual's record.</p> <p>Report any suspected adverse reactions using the Yellow Card System. <a href="#">Yellow Card Scheme - MHRA</a></p>
<p><b>Facilities and supplies required</b></p>	<p>The following are to be available at sites where the vaccine is to be administered:</p> <ul style="list-style-type: none"> <li>• Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit).</li> <li>• An acceptable level of privacy to respect individual's right to confidentiality and safety.</li> <li>• Basic airway resuscitation equipment (e.g. bag valve mask).</li> <li>• Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection.</li> <li>• Access to a working telephone.</li> <li>• Another competent adult, who can summon urgent emergency support if required should ideally be present.</li> <li>• Access to medical support (this may be via the telephone).</li> <li>• Approved equipment for the disposal of used materials.</li> <li>• Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel.</li> <li>• A copy of this PGD in print or electronically.</li> </ul>

**Characteristics of staff authorised to administer vaccine under PGD**

<p><b>Professional qualifications</b></p>	<p>The following classes of registered healthcare practitioners are permitted to administer vaccines as identified and included in individual Board immunisation delivery plans:</p> <ul style="list-style-type: none"> <li>• Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).</li> <li>• Pharmacists currently registered with the General Pharmaceutical Council (GPhC).</li> <li>• Chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC).</li> </ul>
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	<ul style="list-style-type: none"> <li>• Dental hygienists and dental therapists registered with the General Dental Council.</li> <li>• Optometrists registered with the General Optical Council.</li> </ul>
<p><b>Specialist competencies</b></p>	<p><b>Approved by the organisation as:</b></p> <ul style="list-style-type: none"> <li>• Competent to assess the individual's/parent's/carer's capacity to understand the nature and purpose of vaccination in order to give or refuse consent.</li> <li>• Familiar with the vaccine product and alert to changes in the product information.</li> <li>• Competent to undertake administration of the vaccine and discuss issues related to vaccination.</li> <li>• Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.</li> <li>• Competent in the handling and storage of vaccines, and management of the "cold chain".</li> <li>• Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.</li> </ul>
<p><b>Ongoing training and competency</b></p>	<p><b>All professionals working under this PGD must:</b></p> <ul style="list-style-type: none"> <li>• Have undertaken NoS PGD module training on <a href="#">TURAS Learn</a>.</li> <li>• Have attended basic life support training either face to face or online and updated in-line with individual Board requirements.</li> <li>• Have undertaken immunisation training.</li> <li>• Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements.</li> <li>• Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. <b>Note:</b> All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the vaccine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD.</li> <li>• Have knowledge and familiarity of the following;             <ul style="list-style-type: none"> <li>○ Current edition of the <a href="#">Green Book</a></li> <li>○ <a href="#">SmPC</a> for the vaccine to be administered in accordance with this PGD</li> <li>○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board</li> <li>○ Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).</li> </ul> </li> </ul>

<p><b>Responsibilities of professional manager(s)</b></p>	<p><b>Professional manager(s) will be responsible for;</b></p> <p>Ensuring that the current PGD is available to all staff providing care under this direction.</p> <p>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</p> <p>Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.</p>
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**Documentation**

<p><b>Authorisation of administration</b></p>	<p>Qualified registered healthcare professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following:</p> <p>Nurses, midwives and health visitors can be authorised by their line manager.</p> <p>Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration.</p> <p>The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists.</p> <p>All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (<a href="#">Appendix 1</a>).</p> <p>A Certificate of Authorisation (<a href="#">Appendix 2</a>) 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.</p>
<p><b>Record of administration</b></p>	<p>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:</p>

	<ul style="list-style-type: none"> <li>• Date and time of vaccine administration</li> <li>• Individuals name, address and CHI</li> <li>• GP with whom the individual is registered</li> <li>• Exclusion criteria, record why the vaccine was not administered (if applicable)</li> <li>• Record that valid consent to treatment under this PGD was obtained</li> <li>• The name, brand, dose, form, batch number, expiry date, route/and anatomical site of the vaccination administered</li> <li>• Advice given, including advice given if excluded or declined vaccination under this PGD</li> <li>• Signature and name in capital letters of the healthcare professional who administered the vaccine, and who undertook the assessment of the individual’s clinical suitability for the vaccine</li> <li>• Record of any adverse effects and the actions taken (advise individuals’ GP/relevant medical practitioner).</li> </ul> <p>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.</p> <ul style="list-style-type: none"> <li>• Individual’s GP records if appropriate</li> <li>• Occupational health systems</li> <li>• Individual service specific systems.</li> </ul> <p>Local policy should be followed with respect to sharing information with the individual’s General Practitioner.</p> <p>All records should be clear, legible and contemporaneous and in an easily retrievable format.</p>
<p><b>Audit</b></p>	<p>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.</p>
<p><b>References</b></p>	<p>Electronic Medicines Compendium  <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a></p> <p>Ambirix® - Date of revision of text 01/01/21, accessed 19/07/22.</p> <p>Twinrix® - Date of revision of text 01/01/21, accessed 19/07/22.</p> <p>Twinrix® Paediatric - Date of revision of text 01/01/21, accessed 19/07/22.</p>



	<p><a href="#">British National Formulary for Children</a> and the <a href="#">British National Formulary</a> accessed 19/07/22.</p> <p>Department of Health (2006): Immunisation against Infectious Disease [Green Book] <a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a></p> <p>Immunisation against Infectious Disease [Green Book] <a href="#">Hepatitis B chapter 18</a></p> <p>Immunisation against Infectious Disease [Green Book] <a href="#">Hepatitis A chapter 17</a></p> <p>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.</p>
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## 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 Combined Inactivated Hepatitis A And Hepatitis B Vaccine For Non-Travel Indications By Approved Healthcare Professionals Nurses And Pharmacists 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: \_\_\_\_\_

**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 they are 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 they understand and are 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 their individual code of professional practice and conduct.

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 Approved Healthcare Professionals Nurses And Pharmacists 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:**

<b>Name of Healthcare Professional</b>	<b>Signature</b>	<b>Date</b>	<b>Name of Manager</b>	<b>Signature</b>	<b>Date</b>

**Patient Group Direction For The Administration Of Combined Inactivated  
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Isles**

<b>Name of Healthcare Professional</b>	<b>Signature</b>	<b>Date</b>	<b>Name of Manager</b>	<b>Signature</b>	<b>Date</b>