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## HepA/B Vaccine Patient Group Direction (PGD)

This PGD is for the administration of hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (HepA/B) vaccine (adsorbed) to individuals requiring protection against hepatitis A and hepatitis B virus in accordance with national recommendations.

This PGD is for use by registered healthcare practitioners identified in [Section 3](#), subject to any limitations to authorisation detailed in [Section 2](#).

Reference no: HepA/B vaccine PGD  
Version no: V03.00  
Valid from: 01 November 2021  
Review date: 01 May 2023  
Expiry date: 31 October 2023

**The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly-funded immunisation in England 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 the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)<sup>1</sup>. **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 within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

**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 UKHSA/ PGD templates for authorisation can be found from:

<https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd>

Any concerns regarding the content of this PGD should be addressed to:  
[immunisation@phe.gov.uk](mailto:immunisation@phe.gov.uk)

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: [england.swscreeningandimms@nhs.net](mailto:england.swscreeningandimms@nhs.net).




<sup>1</sup> This includes any relevant amendments to legislation (such as [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).  
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## Change history

Version number	Change details	Date
V01.00	New PHE HepA/B vaccine PGD	12 October 2017
V02.00	PHE HepA/B vaccine PGD amended to: <ul style="list-style-type: none"> <li>• include additional healthcare practitioners in Section 3</li> <li>• clarify off-label status of the 0, 7, 21-day schedule of Twinrix® Adult when provided to those from 16 to 18 years of age</li> <li>• refer to vaccine incident guidelines in off-label and storage sections</li> <li>• remove reference the protocol for ordering storage and handling of vaccines</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates and updated PHE PGD Policy</li> </ul>	12 September 2019
V03.00	PHE HepA/B vaccine PGD amended to include: <ul style="list-style-type: none"> <li>• examples added to chronic liver disease in criteria for inclusion</li> <li>• addition of individuals under one year of age to exclusion criteria</li> <li>• removal of reference to hepatitis vaccine shortages in additional information</li> <li>• minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates and updated UKHSA PGD Policy</li> </ul>	8 October 2021

## 1. PGD development

This PGD has been developed by the following health professionals on behalf of UKHSA:

Developed by:	Name	Signature	Date
<b>Pharmacist</b> (Lead Author)	Jacqueline Lamberty Lead Pharmacist, Medicines Governance, UKHSA	 J.Y.LAMBERTY	12 October 2021
<b>Doctor</b>	Dr Gayatri Amirthalingam Consultant Epidemiologist, Immunisation, Hepatitis and Blood Safety Department, National Infection Service, UKHSA		12 October 2021
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant, – Immunisation and Countermeasures, UKHSA		12 October 2021

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Group and the UKHSA Quality and Clinical Governance Delivery Board.

### Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHS England and NHS Improvement
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG
Vanessa MacGregor	Consultant in Communicable Disease Control, UKHSA, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHS England and NHS Improvement South (South West)
Gill Marsh	Principal Screening and Immunisation Manager, NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), NHS England and NHS Improvement (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)


## 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 & NHS Improvement (South West)** authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England & NHS Improvement commissioned immunisation services within <ul style="list-style-type: none"> <li>• Bath &amp; North East Somerset, Swindon, and Wiltshire</li> <li>• Bristol, North Somerset, and South Gloucestershire</li> <li>• Cornwall and the Isles of Scilly</li> <li>• Devon</li> <li>• Dorset</li> <li>• Gloucestershire</li> <li>• Somerset</li> </ul>
Limitations to authorisation
This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version authorised by NHS England and NHS Improvement (South West) must be used.
This PGD includes vaccination of individuals across the national immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer immunisation beyond the groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Medical Director, System Improvement and Professional Standards, NHS England and NHS Improvement (South West)	Dr Kheelna Bavalia MRCGP MSc		28 October 2021

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed to [england.swscreeningandimms@nhs.net](mailto:england.swscreeningandimms@nhs.net).

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

<p><b>Qualifications and professional registration</b></p>	<p>Registered professional with one of the following bodies:</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) (Note: This PGD is not relevant to privately provided community pharmacy services)</li> <li>paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC)</li> </ul> <p>The practitioners above must also fulfil the <a href="#">Additional requirements</a> detailed below.</p> <p>Check <a href="#">Section 2 Limitations to authorisation</a> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<p><b>Additional requirements</b></p>	<p>Additionally, practitioners:</p> <ul style="list-style-type: none"> <li>must be authorised by name as an approved practitioner under the current terms of this PGD before working to it</li> <li>must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using PGDs)</li> <li>must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('<a href="#">The Green Book</a>'), and national and local immunisation programmes</li> <li>must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards and Core Curriculum for Immunisation Training</a></li> <li>must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>must be competent in the handling and storage of vaccines, and management of the 'cold chain'</li> <li>must be competent in the recognition and management of anaphylaxis</li> <li>must have access to the PGD and associated online resources</li> <li>should fulfil any additional requirements defined by local policy</li> </ul> <p><b>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</b></p>
<p><b>Continued training requirements</b></p>	<p>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).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from UKHSA and/or NHS England and NHS Improvement and other sources of medicines information.</p> <p>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.</p>

#### 4. Clinical condition or situation to which this PGD applies

<b>Clinical condition or situation to which this PGD applies</b>	<p>Indicated for the active immunisation of individuals against both hepatitis A and B infection in accordance with the recommendations given in <a href="#">Chapter 7</a>, <a href="#">Chapter 17</a> and <a href="#">Chapter 18</a> of Immunisation Against Infectious Disease: 'The Green Book'.</p>
<b>Criteria for inclusion</b>	<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>• intend to travel, where hepatitis A and hepatitis B vaccination is currently recommended for travel by NaTHNaC (see the <a href="#">Travel Health Pro</a> website for country-specific advice on hepatitis A and hepatitis B vaccine recommendations)</li> <li>• have chronic liver disease (including alcoholic cirrhosis, chronic hepatitis B, chronic hepatitis C, autoimmune hepatitis, primary biliary cirrhosis)</li> <li>• have haemophilia or receive regular blood products</li> <li>• are at risk of hepatitis A and B infection because of their sexual behaviour, such as commercial sex workers or men who have sex with men (MSM)</li> <li>• are people who inject drugs (PWID) or those who are likely to progress to injecting (see <a href="#">Chapter 18</a>)</li> </ul>
<b>Criteria for exclusion<sup>2</sup></b>	<p>Individuals for whom valid consent, or 'best-interests' decision in accordance with the <a href="#">Mental Capacity Act 2005</a>, has not been obtained (for further information on consent see <a href="#">Chapter 2</a> of '<a href="#">The Green Book</a>'). The <a href="#">Patient information leaflet</a> (PIL) for the vaccine to be used should be available to inform consent.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are under one year of age</li> <li>• have had a confirmed anaphylactic reaction to a previous dose of hepatitis A or hepatitis B vaccine or to any component of the vaccine (including trace components from the manufacturing process such as neomycin)</li> <li>• are at increased risk of hepatitis A and hepatitis B infection solely because of their occupation</li> <li>• require solely hepatitis B vaccination for overseas travel purposes</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</li> </ul>
<b>Cautions including any relevant action to be taken</b>	<p>Individuals who are immunosuppressed or have HIV infection may not make a full antibody response and revaccination on cessation of treatment/recovery may be required. This should be discussed with the appropriate/relevant specialist.</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>

<sup>2</sup> Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

<p><b>Action to be taken if the patient is excluded</b></p>	<p>Individuals who have had a confirmed anaphylactic reaction to a previous dose of hepatitis A or hepatitis B containing vaccine or any components of the vaccine should be referred to a clinician for specialist advice and appropriate management.</p> <p>Individuals who are solely at occupational risk of hepatitis A and/or B exposure should be referred to their employer's occupational health provider for vaccination.</p> <p>Individuals requiring solely hepatitis B vaccination for overseas travel purposes should be administered hepatitis B in accordance with local policy. However, hepatitis B vaccination for travel is not remunerated by the NHS as part of additional services and is therefore not covered by this PGD unless hepatitis A vaccination is also indicated, and a combined HepA/B vaccine is used.</p> <p>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.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p> <p>Refer the individual to an alternative service or setting for vaccination if appropriate.</p>
<p><b>Action to be taken if the patient or carer declines treatment</b></p>	<p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the <a href="#">Mental Capacity Act 2005</a>, a decision to vaccinate may be made in the individual's best interests. For further information on consent see <a href="#">Chapter 2</a> of '<a href="#">The Green Book</a>'.</p> <p>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications.</p> <p>Document advice given and the decision reached.</p> <p>Inform or refer to the GP as appropriate.</p>
<p><b>Arrangements for referral for medical advice</b></p>	<p>As per local policy</p>

## 5. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	<p>Hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (HepA/B) vaccine (adsorbed), 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 20 micrograms</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 10 micrograms</li> <li>• Ambirix®, suspension for injection in a pre-filled syringe, hepatitis A virus (inactivated) 720 ELISA units and hepatitis B surface antigen 20 micrograms</li> </ul> <p>An appropriate vaccine product should be selected for the patient see <a href="#">Dose and frequency of administration</a> section.</p>
<b>Legal category</b>	<p>Prescription only medicine (POM)</p>
<b>Black triangle ▼</b>	<p>No</p>
<b>Off-label use</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'.</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage</a> section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <a href="#">PHE Vaccine Incident Guidance</a> or any subsequent UKHSA update. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p>
<b>Route / method of administration</b>	<p>Administer by intramuscular injection. The deltoid region of the upper arm may be used in individuals over one year of age.</p> <p>The buttock should not be used because vaccine efficacy may be reduced.</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 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.</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>. Note that administration by routes other than intramuscular administration into the deltoid region of the upper arm may result in suboptimal immune response to the vaccine.</p>

Continued over page



<b>Route / method of administration</b> continued	<p>The suspension for injection may sediment during storage to leave a fine white deposit with a clear colourless layer. Shake the vaccine well before administration to obtain a uniform turbid white suspension.</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>The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>																				
<b>Dose and frequency of administration</b>	<p>Current UK licensed HepA/B vaccines contain different concentrations of antigen (see table below).</p> <table border="1" data-bbox="566 672 1461 1019"> <thead> <tr> <th>Vaccine</th> <th>Age (licenced use)</th> <th>Dose HepA</th> <th>Dose HepB</th> <th>Volume</th> </tr> </thead> <tbody> <tr> <td>Twinrix® Adult</td> <td>16 years or over</td> <td>720 ELISA units</td> <td>20 micrograms</td> <td>1.0ml</td> </tr> <tr> <td>Twinrix® Paediatric</td> <td>One to 15 years</td> <td>360 ELISA units</td> <td>10 micrograms</td> <td>0.5ml</td> </tr> <tr> <td>Ambirix®</td> <td>One to 15 years</td> <td>720 ELISA units</td> <td>20 micrograms</td> <td>1.0ml</td> </tr> </tbody> </table> <p><b>Licensed dose to provide Hepatitis A and B protection</b></p> <p>Twinrix® Adult: 1ml administered at 0, 1 and 6 months*.</p> <p>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 (see <a href="#">Off-label Use Section</a>). When this schedule is applied, a fourth dose is recommended 12 months after the first dose.</p> <p>Twinrix® Paediatric: 0.5ml administered at 0, 1 and 6 months*</p> <p>Ambirix®: 1ml administered at 0 and 6-12 months*</p> <p>*where 0 is the elected start date of the course</p> <p>For travellers, vaccine should preferably be given at least two weeks before departure but can be given up to the day of departure.</p>	Vaccine	Age (licenced use)	Dose HepA	Dose HepB	Volume	Twinrix® Adult	16 years or over	720 ELISA units	20 micrograms	1.0ml	Twinrix® Paediatric	One to 15 years	360 ELISA units	10 micrograms	0.5ml	Ambirix®	One to 15 years	720 ELISA units	20 micrograms	1.0ml
Vaccine	Age (licenced use)	Dose HepA	Dose HepB	Volume																	
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Ambirix®	One to 15 years	720 ELISA units	20 micrograms	1.0ml																	
<b>Duration of treatment</b>	Dependent of vaccine schedule, see <a href="#">Dose and frequency of administration</a> .																				
<b>Quantity to be supplied / administered</b>	Dose of 0.5ml to 1.0ml per an administration depending on the age of the individual and vaccine product used, see <a href="#">Dose and frequency of administration</a> .																				
<b>Supplies</b>	<p>HepA/B vaccine is not usually centrally supplied and should be obtained directly from manufacturers/wholesalers.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book <a href="#">Chapter 3</a>).</p>																				
<b>Storage</b>  Continued over page	Store at between +2°C to +8°C. Store in original packaging to protect from light. Do not freeze.																				

<b>Storage</b> (continued)	<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, refer to <a href="#">PHE Vaccine Incident Guidance</a> or any subsequent UKHSA update.</p>
<b>Disposal</b>	<p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant ‘sharps’ box, according to local authority arrangements and guidance in the <a href="#">technical memorandum 07-01: Safe management of healthcare waste</a> (Department of Health, 2013).</p>
<b>Drug interactions</b>	<p>Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.</p> <p>May be given at the same time as other vaccines.</p> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<b>Identification &amp; management of adverse reactions</b>	<p>Adverse reactions to hepatitis vaccines are usually mild and confined to the first few days after immunisation. The most common reactions are mild, transient pain, redness and swelling at the injection site.</p> <p>Other commonly reported reactions to hepatitis A vaccination 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>Hypersensitivity reactions and anaphylaxis can occur but are very rare.</p> <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<b>Reporting procedure of adverse reactions</b>	<p>Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <a href="#">Yellow Card reporting scheme</a> or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Any adverse reaction to a vaccine should be documented in the individual’s record and the individual’s GP should be informed.</p>
<b>Written information to be given to patient or carer</b>	<p>Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p>
<b>Patient advice / follow up treatment</b>  Continued over page	<p>Inform the individual/parent/carer of possible side effects and their management.</p> <p>The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>When applicable, advise individual/parent/carer when the subsequent dose is due.</p>

<p><b>Patient advice / follow up treatment</b> (continued)</p>	<p>When administration is postponed advise the individual/parent/carer when to return for vaccination.</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><b>Special considerations / additional information</b></p>	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.</p> <p>There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated vaccines. Since HepA/B vaccine is an inactivated vaccine, the risks to the foetus are negligible and it should be given where there is a definite risk of infection.</p> <p>Monovalent vaccine is preferred where vaccination is recommended post-exposure or for outbreak/incident management.</p> <p>HepA/B vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis C and hepatitis E viruses.</p>
<p><b>Records</b></p>	<p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the <a href="#">Mental Capacity Act 2005</a></li> <li>• name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP)</li> <li>• name of immuniser</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if excluded or declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via PGD</li> </ul> <p>Records should be signed and dated (or a password-controlled immuniser's record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Service (CHIS) using the appropriate documentation/pathway as required by any local or contractual arrangement.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

## 6. Key references

<b>Key references</b>	<p><b>Product</b></p> <ul style="list-style-type: none"><li>• Immunisation Against Infectious Disease: The Green Book <a href="#">Chapter 4</a>, updated June 2012, <a href="#">Chapter 7</a>, updated 10 January 2020, <a href="#">Chapter 17</a>, updated December 2013 and <a href="#">Chapter 18</a>, updated June 2017. <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></li><li>• Summary of Product Characteristic for Twinrix® Adult, GlaxoSmithKline UK. Last updated 1 January 2021 <a href="https://www.medicines.org.uk/emc/medicine/2061">https://www.medicines.org.uk/emc/medicine/2061</a></li><li>• Summary of Product Characteristic for Twinrix® Paediatric, GlaxoSmithKline UK. Last updated 1 January 2021 <a href="https://www.medicines.org.uk/emc/medicine/2062">https://www.medicines.org.uk/emc/medicine/2062</a></li><li>• Summary of Product Characteristic for Ambirix®, GlaxoSmithKline UK. Last updated 12 March 2021 <a href="https://www.medicines.org.uk/emc/medicine/20491">https://www.medicines.org.uk/emc/medicine/20491</a></li><li>• <a href="#">NaTHNaC</a> resources. Accessed 20 September 2021. <a href="https://travelhealthpro.org.uk/countries">https://travelhealthpro.org.uk/countries</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. <a href="https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/">https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/</a></li><li>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. <a href="https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li><li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. <a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li><li>• UKHSA Immunisation Collection <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• PHE Vaccine Incident Guidance <a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li></ul>
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## 7. Practitioner authorisation sheet

**HepA/B vaccine PGD v03.00 Valid from: 01/11/2021 Expiry: 31/10/2023**

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

### Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs 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 PGD 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 <b>insert name of organisation</b> for the above named healthcare 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.