UK Health Security Agency

NHS

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Hepatitis A and B (Hep A and B) Vaccine Patient Group Direction (PGD)

This PGD is for the administration of combined hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (Hep A and 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:	Hepatitis A and B combined vaccine PGD
Version no:	V4.00
Valid from:	31 October 2023
Review date:	01 May 2023
Expiry date:	31 October 2026

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)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

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

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Vaccination and Screening Programmes, NHS England – Midlands, responsible for your area:

East: england.emids-imms@nhs.net

[1] This includes any relevant amendments to legislation.

- Derby and Derbyshire
- Lincolnshire
- Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: england.wmid-imms@nhs.net

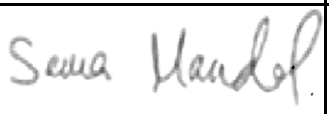
- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford, and Wrekin
- Black Country
- Coventry and Warwickshire

Change history

Version number	Change details	Date
V1.00	New PHE HepA/B vaccine PGD	12 October 2017
V2.00	PHE HepA/B vaccine PGD amended to: • include additional healthcare practitioners in Section 3 • 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 • refer to vaccine incident guidelines in off-label and storage sections • remove reference the protocol for ordering storage and handling of vaccines • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates and updated PHE PGD Policy	12 September 2019
V3.00	PHE HepA/B vaccine PGD amended to include: • examples added to chronic liver disease in criteria for inclusion • addition of individuals under one year of age to exclusion criteria • removal of reference to hepatitis vaccine shortages in additional information • minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates and updated UKHSA PGD Policy	8 October 2021
V4.00	UKHSA Hepatitis A and B combined vaccine PGD amended to include: • potential for reduced antibody titers when co-administered with human normal immunoglobulin (HNIG) or hepatitis B immunoglobulin • confirmation the vaccine cannot be used in post-exposure prophylaxis • advice to maintain the same brand of combined hepatitis A and B throughout the primary vaccination course • details of protection against hepatitis B not being fully conferred until after the second dose of Ambirix® • minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates • replacement of ‘Public Health England’ and ‘PHE’ with UKHSA, including updated contact details	9 October 2023

1. PGD development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist – Immunisation and Vaccine Preventable Diseases Division, UKHSA		5 October 2023
Doctor	Dr Sema Mandal Deputy Director and Consultant Epidemiologist, Blood Safety, Hepatitis, STIs and HIV, UKHSA		5 October 2023
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, , UKHSA		5 October 2023

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.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Rosie Furner	Specialist Pharmacist, Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner, Emergency Care Practitioner, Medicines Manager, Proactive Care Lead, Southbourne Surgery
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nikki Philbin	Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London
Laura Smeaton	IDPS Programme Projects Manager and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme, NHS England (NHSE)

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.

NHSE Midlands authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Primary care services and/or all organisations commissioned or contracted by NHS England – Midlands to provide immunisation services in: • Derby and Derbyshire • Lincolnshire • Leicester, Leicestershire, and Rutland • Northamptonshire • Nottingham and Nottinghamshire • Herefordshire and Worcestershire • Birmingham and Solihull • Staffordshire and Stoke-on-Trent • Shropshire, Telford and Wrekin • Black Country • Coventry and Warwickshire
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director of Primary Care and Public Health Commissioning – NHS England, Midlands	**Trish Thompson**		**10.10.23**

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

Local enquiries regarding the use of this PGD may be directed to Vaccination and Screening Programmes, NHS England – Midlands, responsible for your area:

East: england.emids-imms@nhs.net

- Derby and Derbyshire
- Lincolnshire
- Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: england.wmid-imms@nhs.net

- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- Coventry and Warwickshire

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

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from UKHSA, NHS England and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals against both hepatitis A and B infection in accordance with the recommendations given in Chapter 7, Chapter 17 and Chapter 18 of Immunisation Against Infectious Disease: the Green Book.
Criteria for inclusion	Individuals over 1 year of age requiring Hepatitis A and Hepatitis B pre-exposure prophylaxis including individuals who: • intend to travel, where hepatitis A and hepatitis B vaccination is currently recommended for travel by NaTHNaC (see the Travel Health Pro website for country-specific advice on hepatitis A and hepatitis B vaccine recommendations) • have chronic liver disease (including alcoholic cirrhosis, chronic hepatitis B, chronic hepatitis C, autoimmune hepatitis, primary biliary cirrhosis) • have haemophilia or receive regular blood products • 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) • are people who inject drugs (PWID) or those who are likely to progress to injecting (see Chapter 18)
Criteria for exclusion[2]	Individuals for whom valid consent or best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent, see Chapter 2 of the Green Book). Several resources are available to inform consent (see written information to be given to individual or carer section). Individuals who: • are under one year of age • 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) • are at increased risk of hepatitis A and hepatitis B infection solely because of their occupation • require solely hepatitis B vaccination for overseas travel purposes • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination premises (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). Individuals who are immunosuppressed or have HIV infection may not make a full antibody response and revaccination on cessation of treatment or following recovery may be required. This should be discussed with the relevant specialist. 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.

[2] 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

Action to be taken if the individual is excluded	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. Individuals who are solely at occupational risk of either hepatitis A or B exposure (or both) should be referred to their employer's occupational health provider for vaccination. 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 hepatitis A and B vaccine is used. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the GP or a prescriber as appropriate. Refer the individual to an alternative service or setting for vaccination if appropriate.
Action to be taken if the individual or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Chapter 2 of the Green Book. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and the decision reached. Inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	Hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (HepA/B) vaccine (adsorbed), either: • 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 • 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 • Ambirix®, suspension for injection in a pre-filled syringe, hepatitis A virus (inactivated) 720 ELISA units and hepatitis B surface antigen 20 micrograms An appropriate vaccine product should be selected for the individual (see Dose and frequency of administration).
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	The Twinrix® Adult schedule given at 0, 7 and 21 days is licensed for adults (that is, aged 18 years and above) 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 Chapter 18 of the Green Book. Though the SPCs for each combined vaccine advise that a course of vaccination should be completed with the same brand, if necessary another product may be used to avoid a delay in protection. Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to Vaccine Incident Guidance 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. Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual, parent or carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route and method of administration (continued over page)	Administer by intramuscular injection. The deltoid muscle of the upper arm may be used in individuals over one year of age. The buttock should not be used because vaccine efficacy may be reduced. When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each was given should be noted in the individual's records. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the Green Book Chapter 4. Note that administration by routes other than intramuscular administration into the

<table>
<tr><td>Route and method of administration
(continued)</td><td>deltoid muscle of the upper arm may result in suboptimal immune response to the vaccine.

The suspension for injection may sediment during storage to leave a fine white deposit with a clear colourless layer. Shake the vaccine vigorously before administration to obtain a uniform hazy white suspension.

The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, discard the vial in accordance with local procedures.

The vaccine SPCs provides further guidance on preparation and administration and are available from the electronic Medicines Compendium.</td></tr>
<tr><td>Dose and frequency of administration</td><td>Current UK licensed hepatitis A and B combined vaccines contain different concentrations of antigen (see table below).
<table>
<tr><th>Vaccine</th><th>Age (licensed use)</th><th>Dose HepA</th><th>Dose HepB</th><th>Volume</th></tr>
<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>
</table>
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 (see Off-label use section). When this schedule is applied, a fourth dose is recommended 12 months after the first dose.

Twinrix® Paediatric: 0.5ml administered at 0, 1 and 6 months*

Ambirix®: 1ml administered at 0 and 6 to 12 months*

*where 0 is the elected start date of the course

For travellers, vaccine should preferably be given at least 2 weeks before departure but can be given up to the day of departure.

Note: Where immunisation has been delayed beyond the recommended intervals outlined , the vaccine course should be resumed and completed.

It is preferred that the primary course of vaccination is completed with the same vaccine brand throughout. The course may be completed with a different vaccine to avoid a delay in protection.</td></tr>
<tr><td>Duration of treatment</td><td>Dependent on vaccine product and schedule, see Dose and frequency of administration above.</td></tr>
<tr><td>Quantity to be supplied and administered</td><td>Dose of 0.5ml to 1.0ml per administration, depending on the age of the individual and vaccine product used (see Dose and frequency of administration).</td></tr>
</table>

Supplies	Hepatitis A and B combined vaccine is not usually centrally supplied and should be obtained directly from manufacturers or their wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).
Storage	Store at between +2°C to +8°C. Store in original packaging to protect from light. Do not freeze. 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 Vaccine Incident Guidance or any subsequent UKHSA update.
Disposal	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 NHSE guidance (HTM 07-01): Management and disposal of healthcare waste.
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines. A detailed list of drug interactions associated with the combined hep A and B vaccines are provided in the respective SPCs, available from the electronic Medicines Compendium.
Identification and management of adverse reactions	Adverse reactions to combined hepatitis A and B vaccines are usually mild and confined to the first few days after immunisation. Very common reactions include mild, transient pain and redness at the injection site, headache and fatigue. Other commonly reported reactions include other injection-site reactions such as bruising and swelling, general symptoms such as fever, malaise, loss of appetite, irritability and drowsiness, and gastrointestinal symptoms such as nausea and diarrhoea. Hypersensitivity reactions and anaphylaxis can occur but are very rare. A detailed list of adverse reactions associated with combined hep A/B vaccines is available from the electronic Medicines Compendium.
Reporting procedure of adverse reactions	Healthcare professionals and individuals, parents and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme, or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to individual or carer (continued over page)	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. For resources in accessible formats and alternative languages, please visit Home- Health Publications. Where applicable, inform the individual or carer that large print, Braille

Written information to be given to individual or carer (continued)	or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the electronic Medicines Compendium.
Advice and follow up treatment	Inform the individual, parent or carer of possible side effects and their management. The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card reporting scheme. When applicable, advise individual, parent or carer when the subsequent dose is due. When administration is postponed advise the individual, parent or carer when to return for vaccination. 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).
Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated vaccines. Since combined hepatitis A and B vaccine is an inactivated vaccine, the risks to the fetus are negligible and it should be given where there is a definite risk of infection. In situations where a booster dose of hepatitis A, hepatitis B or both is desired, either monovalent or combined hepatitis A and hepatitis B vaccines may be given. The combined vaccine should not be used for post-exposure prophylaxis, such as in managing needlestick injuries. Monovalent vaccine should be given where vaccination is recommended for post-exposure or for management of outbreaks or incidents. Hepatitis A and B combined vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis C and hepatitis E viruses. Individuals, their parent or carer should be advised that protection against hepatitis B may not be obtained until after the second dose of Ambirix®. Therefore Ambirix® should be used only where there is a relatively low risk of hepatitis B infection during the vaccination course.
Records (continued over page) **Records**	The practitioner must ensure the following is recorded: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005 • 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) • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered

(continued)	• batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous. When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Service (CHIS) using the appropriate documentation or pathway as required by any local or contractual arrangement. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Product** • Immunisation Against Infectious Disease: The Green Book Chapter 4, updated June 2012, Chapter 7, updated 10 January 2020, Chapter 17, updated 7 February 2022 and Chapter 18, updated 7 February 2022 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Twinrix® Adult, GlaxoSmithKline UK. Last updated 21 July 2023 https://www.medicines.org.uk/emc/medicine/2061 • Summary of Product Characteristic for Twinrix® Paediatric, GlaxoSmithKline UK. Last updated 21 July 2023 https://www.medicines.org.uk/emc/medicine/2062 • Summary of Product Characteristic for Ambirix®, GlaxoSmithKline UK. Last updated 21 July 2023 https://www.medicines.org.uk/emc/medicine/20491 • NaTHNaC resources. Accessed 20 September 2023. https://travelhealthpro.org.uk/countries **General** • NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023. https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Last updated March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017 https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance. Last updated July 2022 https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

Hepatitis A and B combined vaccine PGD v4.00
Valid from: 31 October 2023 Expiry: 31 October 2026.

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 **insert name of organisation** 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.