



Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

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

by registered healthcare practitioners

in Powys Teaching Health Board or Powys GP practices

Version number: PGD 0238

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Change History

Version number	Change details	Date
PGD 0238	Initial issue produced using UKHSA template v04.00	08/11/2023

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This Powys Teaching Health Board PGD is based on a template developed by the following health professionals on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy (also ratified by the UKHSA Medicines Governance Group).

Developed by the following health professionals on behalf of the UKHSA:

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

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 Lockett	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 Advisor, NHSE London
Laura Smeaton	IDPS Programme Projects Manager and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme, NHS England (NHSE)

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PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor Dr Kate Wright	Lead doctor for PTHB	DocuSigned by: <i>Kate Wright</i> 1F267952823F473...	11/27/2023
Chief Pharmacist Jacqui Seaton	Chief Pharmacist for PTHB	DocuSigned by: <i>Jacqui Seaton</i> 71E8089DE3634C4...	11/7/2023
Senior representative of professional group using the PGD Claire Roche	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: <i>Claire Roche</i> FC9C4C63FC374A7...	11/20/2023
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: <i>Amanda Edwards</i> 74A4E51A42E9473...	11/29/2023

[Appendix A](#) provides a staff accreditation sheet. Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Those using this PGD must ensure that it is organisationally authorised and signed 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](#).**

The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

¹ This includes any relevant amendments to legislation

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PGD adoption by the provider

Name	Job title and organisation	Signature	Date

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1. Characteristics of staff

<p>Qualifications and professional registration</p>	<p>Practitioners must only work under this PGD where they are competent to do so. Practitioners working under this PGD must also be a registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> • 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) <p>The practitioners above must also fulfil the Additional requirements detailed below.</p> <p>Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<p>Additional requirements</p>	<p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • 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 have completed Patient Group Directions training (available via ESR at https://my.esr.nhs.uk or eLearning for Healthcare (e-LfH) at http://www.e-lfh.org.uk/programmes/patient-group-directions/) • 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 and online training. Please contact PTHB immunisation co-ordinator for further information. • must be competent to undertake immunisation and to discuss issues related to immunisation

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	<ul style="list-style-type: none"> • must be competent in the handling and storage of vaccines, and management of the cold chain. Completion of cold chain training via https://www.youtube.com/watch?v=m2tDUgV-roE (also available via ESR) • must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines • must be competent in the recognition, management and reporting of adverse drug reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Life Support skills (Basic Life Support Skills are PTHB standard). • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</p>
<p>Continued training requirements</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>Evidence of ongoing PGD training to be submitted to Line Manager annually.</p> <p>Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. Practitioners must make a self-declaration of competency on PADR.</p> <p>Compliance with all mandatory NHS training.</p> <p>Practitioners should be constantly alert to any subsequent recommendations from UKHSA, NHS England and/or Welsh Government and/or Public Health Wales and/or NHS Wales 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.</p> <p>It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.</p>

2. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<p>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.</p> <p>It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.</p>
<p>Criteria for inclusion</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"> • 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) • Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained prior to administration. • Medical and drug history taken, no reason for exclusion <p>NB. Refer to PTHB Consent to Treatment and Examination Policy</p>
<p>Criteria for exclusion (Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit)</p>	<p>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). Refer to sections "Action to be taken if the individual is excluded" and "Action to be taken if the individual or carer declines treatment".</p>

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<p>and another form of authorisation will be required)</p>	<p>Individuals who:</p> <ul style="list-style-type: none"> • 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)
<p>Cautions including any relevant action to be taken</p>	<p>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).</p> <p>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.</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. Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP.</p> <p>Any safeguarding concerns need to be directed to Safeguarding Hub:</p> <ul style="list-style-type: none"> • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk <p>and</p> <ul style="list-style-type: none"> • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847

	Advice can also be sought from local Safeguarding Leads
Action to be taken if the individual is excluded	<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 either hepatitis A or B exposure (or both) 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 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, PTHB Infection Control 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>
Action to be taken if the individual or carer declines treatment	<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 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.</p>

	<p>Advise the individual, parent or 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>Inform child health if appropriate – if any vaccination is declined for a child under 19 years of age, child health must be informed and the appropriate form completed.</p>
Arrangements for referral for medical advice	<p>Refer to GP or consultant in communicable disease control (CCDC) for clinical advice as necessary.</p> <p>Document any advice given.</p>

3. Description of treatment

Name, strength and formulation of drug	<p>Hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (HepA/B) vaccine (adsorbed), either:</p> <ul style="list-style-type: none"> • 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 <p>An appropriate vaccine product should be selected for the individual (see Dose and frequency of administration).</p>
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

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	<p>PWID) in accordance with Chapter 18 of The Green Book.</p> <p>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.</p> <p>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 the All Wales Advisory document on Ordering Storage and Handling of Vaccines and 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.</p> <p>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.</p>
<p>Route and method of administration</p>	<p>Administer by intramuscular injection. The deltoid muscle of the upper arm may be used in individuals over one year of age (see The Green Book Chapter 4). 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 Chapter 4. Note that administration by routes other than intramuscular administration into the deltoid muscle of the upper arm may result in suboptimal immune response to the vaccine.</p>

	<p>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.</p> <p>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.</p> <p>The vaccine SPCs provides further guidance on preparation and administration and are available from the electronic Medicines Compendium website: www.medicines.org.uk</p>																				
<p>Dose and frequency of administration</p>	<p>Current UK licensed hepatitis A and B combined vaccines contain different concentrations of antigen (see table below).</p> <table border="1" data-bbox="523 913 1437 1384"> <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>Licensed dose to provide Hepatitis A and B protection 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 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*</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																	
Twinrix® Adult	16 years or over	720 ELISA units	20 micrograms	1.0ml																	
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Ambirix®	One to 15 years	720 ELISA units	20 micrograms	1.0ml																	

	<p>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.</p> <p>Note: Where immunisation has been delayed beyond the recommended intervals outlined, the vaccine course should be resumed and completed.</p> <p>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.</p>
Duration of treatment	Dependent of vaccine product and schedule, see Dose and frequency of administration above.
Quantity to be administered	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).
Supplies	<p>Hepatitis A and B combined vaccine is not usually centrally supplied and should be obtained directly from manufacturers or their wholesalers.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).</p> <p>Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.</p>
Storage	<p>Store at between +2°C to +8°C. Store in original packaging to protect from light. Do not freeze.</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>Refer to Vaccine Incident guidance or any subsequent UKHSA update, or protocols for the storage and handling of vaccines (see All Wales Advisory document on Ordering Storage and Handling of Vaccines and Green Book Chapter 3).</p>

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	Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation co-ordinator (Powys.Immunisations@wales.nhs.uk), and via the Once for Wales Reporting System .
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) and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste .
Drug interactions	<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. 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 website http://www.medicines.org.uk.</p>
Identification and management of adverse reactions	<p>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.</p> <p>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.</p> <p>Hypersensitivity reactions and anaphylaxis can occur but are very rare.</p> <p>A detailed list of adverse reactions associated with combined hep A/B vaccines is available from the electronic Medicines Compendium website: http://www.medicines.org.uk.</p>

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	<p>In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone.</p> <p>In case of anaphylaxis: -</p> <ul style="list-style-type: none"> • Refer to adrenaline (epinephrine) PGD and anaphylaxis policy <ul style="list-style-type: none"> • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked ALLERGIC TO combined hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (Hep A and B) vaccine (adsorbed) • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers <p>Report via Once for Wales Reporting System.</p>
<p>Reporting procedure of adverse reactions</p>	<p>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 at: http://yellowcard.mhra.gov.uk or by searching 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> <p>All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System.</p>
<p>Written information to be given to individual or carer</p>	<p>Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Information for printing and website links suitable for patients can be found on NHS 111 Wales and Public Health Wales Health Information Resources.</p> <p>For resources in accessible formats and alternative</p>

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	<p>languages, please visit Home- Health Publications. Where applicable, inform the individual or carer that large print, Braille 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.</p>
<p>Advice and follow up treatment</p>	<p>Give appropriate advice if medication is used off-label. Inform the individual, parent or carer of possible side effects and their management.</p> <p>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.</p> <p>When applicable, advise individual, parent or carer when the subsequent dose is due.</p> <p>When administration is postponed advise the individual, parent or 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>Special considerations and additional information</p>	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a working 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 combined hepatitis A and 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>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.</p>

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	<p>Monovalent vaccine should be given where vaccination is recommended for post-exposure or for management of outbreaks or incidents.</p> <p>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.</p> <p>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.</p>
<p>Records</p>	<p>Record consultation details as required by local procedures. The practitioner must ensure the following is recorded:</p> <ul style="list-style-type: none"> • 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 • 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 • administered via PGD, record PGD version number <p>Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous.</p> <p>This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed.</p>

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	<p>When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Service (CHIS) (Child Health Records Department) using the appropriate documentation or pathway as required by any local or contractual arrangement (based in Brecon Hospital for under 5 years and Llandrindod Hospital for school age).</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>
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4. Key references

Key references	Product
	<ul style="list-style-type: none"> • 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 <p>General</p> <ul style="list-style-type: none"> • NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023. https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste • 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. Published 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

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	<ul style="list-style-type: none">• Vaccine Incident Guidance. Last updated July 2022. https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors• All Wales Advisory document on Ordering Storage and Handling of Vaccines 7th Edition September 2017• Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste• WHC/2023/001. Eliminating hepatitis (B and C) as a public health threat in Wales – Actions for 2022-23 and 2023-24
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Appendix A – Staff Accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager may wish to use the competency checklist (below).*

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 Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Printed name of health professional	Signature of health professional	Printed name of senior representative authorising health professional (Authorising Manager)	Signature of senior representative authorising health professional (Authorising Manager)	Date

The authorising manager should retain a copy of the list and a copy must be sent to the Medicines Management Team, PTHB, Bronllys Hospital, Powys LD3 0LU for audit purposes.

The healthcare professional should retain a copy of the document after signing.

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Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: Role:		Sign / Initial	Further training identified (Y/N) Specify in " comments	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager, to the staff member, and to medicines management department (info.medicinesmanagement.powys@wales.nhs.uk), in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.

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