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

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

Lead Author: Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/HepAB/ MGPG1174	**Review Date:** August 2023 **Expiry Date:** August 2024	**Date Approved:** August 2021

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

Uncontrolled when printed

Version 2

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NoS/PGD/hepAB/MGPG955 Version 1.1	
Date of change	**Summary of Changes**	**Section heading**
May 2021	Short-term foster carers removed as an inclusion, they are included in Hep B PGD.	Inclusion criteria
May 2021	Latex allergy removed from exclusion criteria as none of the vaccines contains latex.	Exclusion criteria
May 2021	Updated information added relating to Twinrix® Paediatric as per SmPC update.	Route/Method of administration
May 2021	Updated information added relating to Ambirix® Paediatric as per SmPC update.	Dosage/Maximum total dosage

NoS Identifier: NoS/PGD/hepAB/MGPG1174,
Keyword(s): PGD Patient Group Direction Hepatitis A Hepatitis B Combined Vaccine Nurse Pharmacist

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

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	May 2021
	Completed:	August 2021
	Approved:	August 2021(published - August 2021)
	Amended:	

Organisational Authorisations

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

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Diana Webster **Health Board:** NHSG **Title:** Public Health Consultant **Contact email:** diana.webster@nhs.scot **Signature** ..DWebster.....
Senior representative of the professional group who will provide care under the direction.	**Name:** Lynda Davidson **Health Board:** NHSH **Title:** Health Protection Nurse Specialist **Contact email:** lynda.davidson@nhs.scot **Signature** .....Lynda Davidson.....
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature** .....FAdamson.....
Pharmacist	**Name:** Russell MacKay **Health Board:** NHSO **Title :** HEPMA and Systems Lead Pharmacist **Contact email:** russell.mackay@nhs.scot **Signature** .....Russ.....

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		04/08/2021

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		26/08/2021

Management and Monitoring of Patient Group Direction

PGD Consultative Group

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

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Russell Mackay	**Pharmacist:** HEPMA and Systems Lead Pharmacist NHSO
Dr Diana Webster	**Medical Practitioner:** Public Health Consultant NHSG
Lynda Davidson	**Senior Representative:** Health Protection Nurse Specialist NHSH
Liam Callaghan	Chief Pharmacist NHSWI
Tina McMichael	Advanced Nurse Specialist (Health Protection) NHST
Linda Stewart	Immunisation Nurse NHSG

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Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer combined inactivated hepatitis A and hepatitis B vaccine to individuals for active immunisation against both hepatitis A and hepatitis B (HepAB). This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book, TRAVAX, NaTHNaC and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Individuals over 1 year of age at risk of both hepatitis A and hepatitis B infection requiring prophylaxis who: • Intend travelling to areas of moderate or high endemicity for prolonged periods. Includes those posted to, or going to reside in virus endemic countries, dependant on risk assessment • Are laboratory staff who are working directly with the viruses and those at occupational risk after risk assessment where there is a need for the administration of both HepAB to be given at the same time • Are staff and residents of residential institutions (after local risk assessment) • Are at risk due to sexual behaviour, e.g. men who have sex with men, those who change sexual partners frequently • Are haemophiliacs and those receiving regular blood transfusions or blood products and carers responsible for administration of these products • Have chronic liver disease, including those with milder liver disease, particularly those infected with hepatitis C • Are injecting drug users, their sexual partners, and household contacts, including children, and those who are likely to progress to injecting drugs • Are families adopting children from countries with high or intermediate prevalence of both HepAB • Are groups of individuals as identified by the local Board Health Protection Team • Are children requiring booster dose(s) 6 months after completing chemotherapy.

	Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals: • Under 1 year of age. • Confirmed anaphylactic reaction to a previous dose of the vaccine or to a previous dose of either Hep A or Hep B vaccines individually. • Known anaphylactic hypersensitivity to any of the excipients or neomycin. • If the individual has had a significant local or general allergic reaction to a previous administration of combined HepAB- a doctor should be consulted. • Individuals suffering from acute severe febrile illness (minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered). • Individuals with impaired immunity, either because of disease or treatment. The response may be suboptimal and additional doses of vaccine may be required – specialist advice is required. Not covered by this PGD. • Where there is no valid consent.
Precautions and special warnings	Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. The vaccine should be administered with caution in individuals with thrombocytopenia or a bleeding disorder since bleeding may follow IM injection. In these individuals, vaccination can be administered by deep subcutaneous injection to reduce the risk of bleeding although there is an increased risk of local reactions (Green Book recommendation). A number of factors may reduce the immune response to hepatitis B vaccines. These include age over 40 years, obesity and smoking. Lower seroconversion rates have also been reported in alcoholics. Consideration should be given to serological testing of these subjects who may be at risk of not achieving seroprotection following a complete course of vaccination. Additional doses may be needed, not covered by this PGD.

	Pregnancy and lactation – There is no evidence of risk from vaccinating pregnant women or those who are breastfeeding. Immunisation should not be withheld from a pregnant woman if she is in the high-risk category.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. If clarification is required about an individual meeting the exclusion criteria advice can be sought from the local Health Protection team. The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached. Inform/refer to the relevant medical practitioner if individual/person with parental responsibility declines treatment. Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.

Description of vaccine available under the PGD

Name form and strength of vaccine	Ambirix® (for those aged 1 to 15 years of age). 1mL pre-filled syringe containing inactivated hepatitis A virus 720 ELISA Units and hepatitis B virus surface antigen recombinant 20 micrograms. It is a turbid white suspension for injection. Twinrix® Paediatric Vaccine (for those aged 1 to 15 years of age). 0.5mL pre-filled syringe containing inactivated hepatitis A virus 360 ELISA Units and hepatitis B virus surface antigen recombinant 10 micrograms. It is a turbid, white suspension for injection.

	Twinrix® Adult Vaccine (for those aged 16 years of age and over). 1mL pre-filled syringe containing inactivated hepatitis A virus 720 ELISA Units and hepatitis B virus surface antigen recombinant 20 micrograms. It is a turbid, white suspension for injection.
Legal status	Ambirix® and Twinrix® are Prescription-only Medicines (PoM).

Dosage/Maximum total dose

Combined Hepatitis A and Hepatitis B Vaccine for Adults & Children: TRAVAX Information Summary Table (2020)

	Twinrix® Adult	**Twinrix® Paediatric**	***Ambirix® Paediatric**
Age	From 16 years	From 1 year - up to and including 15 years	From 1 year - up to and including 15 years
Dosage	1mL	0.5mL	1mL
Standard Schedule	3 Doses • 0 • + 1 month • + 6 months	3 Doses • 0 • + 1 month • + 6 months	2 Doses (children only) • 0 • + 6 - 12 months
Very Rapid Schedule	4 Doses • 0 • + 7 days • + 21 days • + 12 months Indicated when rapid protection against Hep B is required.	No very rapid schedule	No very rapid schedule

***NOTE**: Ambirix® should be used only when there is a relatively low risk of hepatitis B infection during the vaccination course. It is recommended that Ambirix® should be administered in settings where completion of the two-dose vaccination course can be assured.

Booster Doses
Following complete schedules for individuals who remain at continued risk:

NOTE: Single component vaccines should be used.

Hepatitis A
- Single booster with monovalent hepatitis A vaccine 25 years after primary course, (i.e. at 25 yearly intervals).

Hepatitis B

- Single booster dose of hepatitis B only once, around 5 years after primary course.

Additional information:
A single dose of monovalent hepatitis A vaccine will provide more rapid protection than the combined preparations where more than one dose is required.

In situations where a booster dose of hepatitis A and/or hepatitis B is desired a monovalent or combined vaccine can be given. If rapid protection against hepatitis A is required for adults, e.g. following exposure or during outbreaks, then a single dose of monovalent vaccine is recommended.

Frequency of dose/Duration of treatment	See Dose/Maximum total dose.
Maximum or minimum treatment period	N/A
Route/Method of administration	The HepAB vaccine should **not** be given by the intravenous or intradermal routes under any circumstances. This vaccine should **not** to be administered in the gluteal muscle or intradermally since this may result in lower immune response. Administration should be given by **Intramuscular (IM) Injection** preferably into the deltoid muscle or in the anterolateral thigh in infants. 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 (American Academy of Paediatrics 2003). The site at which each vaccine was given should be noted in the individual's records. **NOTE:** Twinrix® Paediatric should not be given at the same time as any other vaccine. However, it can be given concomitantly with Human Papillomavirus (HPV) vaccine only. Individuals with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding.

	The vaccine should be allowed to reach room temperature before use. Upon storage, a fine white deposit with a clear colourless layer above may be observed. The vaccine should be re-suspended before use. When re-suspended, the vaccine will have a uniform hazy white appearance. The vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance prior to administration. In the event of either being observed, do not administer the vaccine and discarded in its entirety.
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 Dosage/Maximum total Dose section.
Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Store in original packaging in order to protect from light. Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed.
Follow-up (if applicable)	Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice. Where proof of vaccination is required, a certificate, stamped vaccination booklet or equivalent must be supplied.
Advice (Verbal)	Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions. If serious adverse or persistent effects occur, the individual/person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24. When administration is postponed advise the individual/person with parental responsibility when to return for vaccination.

Advice (Written)	The PIL contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. More information regarding this vaccine can be found at: https://www.nhsinform.scot/healthy-living/immunisation
Identifying and managing possible adverse reactions	Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. Other reactions commonly reported: • Individuals may also experience stiffness of the muscle injected for a few days following vaccination • Headache, fatigue, nausea, malaise, decreased appetite (rare with Twinrix® Adult) • Drowsiness, fever, irritability (Ambirix® and Twinrix® Paediatric); Diarrhoea (uncommon in Twinrix® Paediatric). **This list is not exhaustive. Please also refer to current BNFC/BNF and manufacturers SmPC for details of all potential adverse reactions.** **BNFC/BNF**: https://www.bnf.org/products/bnf-online/ **SmPC/PIL/Risk Minimisation Material:** https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm https://www.medicines.org.uk/emc/rmm-directory If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the MHRA using the Yellow Card System https://yellowcard.mhra.gov.uk/.

Facilities and supplies required	The following are to be available at sites where the vaccine is to be administered: • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. pocket mask, bag valve mask, supraglottic airway) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	Registered Nurses as recognised by the Nursing and Midwifery Council (NMC), and Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/person with parental responsibilities capacity to understand the nature and purpose of vaccination in order to give or refuse consent • Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken PGD training as required/set out by each individual Health Board • Have attended basic life support training either face to face or online and updated in-line with individual Board requirements • Have undertaken immunisation training where available • Have undertaken NHS e-anaphylaxis training or equivalent (including annual updates) which covers all aspects of the identification and management of anaphylaxis

	• Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct
	• Have knowledge and familiarity of the following;
	  ○ Current edition of the Green Book
	  ○ SmPC for the vaccine to be administered in accordance with this PGD
	  ○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board
	  ○ Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).

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

Documentation

Authorisation of administration	Nurses working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the vaccine specified in this PGD by their Professional Line Manager/Consultant/Practice GP. Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of administration	An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:

	• Date and time of vaccine administration • Individuals name and CHI • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/site of the vaccination administered • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate. • Individual's GP records if appropriate • Occupational health systems • Individual service specific systems.
Audit	All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Ambirix® - Date of revision of text 01/01/21, accessed 05/05/21. Twinrix® - Date of revision of text 01/01/21, accessed 05/05/21. Twinrix® Paediatric - Date of revision of text 01/01/21, accessed 05/05/21. British National Formulary for Children and the British National Formulary https://about.medicinescomplete.com/ accessed 05/05/21.

	Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Green Book chapters 17 (Hepatitis A) and 18 (Hepatitis B) Travax http://www.travax.nhs.uk/accessed 05/05/21. American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.

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

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

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

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

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

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

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

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

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

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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