Patient Group Direction (PGD)

Administration of hepatitis A and B vaccine for travel indications

Publication date: 01 February 2022

Version 1.0
Effective from: 01 February 2022
Review date: 31 January 2024

Version history

Version	Date	Summary of changes
1.0	01/02/22	Version 1.0 new PGD

Contents

Authorisation

PGD Hepatitis A and B vaccine for travel indications

This Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS boards. NHS Borders has ensured that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer hepatitis A and B vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/summary of product characteristics (SPC) for all vaccines administered in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS Borders by:

Doctor ….Dr Tim Patterson…….... **Signature** 

Pharmacist ….Adrian Mackenzie…… **Signature** 

Nurse ……Jill Madden…… **Signature** 

Approved on behalf of NHS Borders by:

Medical Director ……Dr Lynn McCallum…… **Signature** 

Director of Pharmacy/
Senior Pharmacist ……Alison Wilson…… **Signature** 

Clinical Governance Lead …Sarah Horan…… **Signature** 

Date approved: 21/02/2022

Effective from: 01/02/2022 **Review date:** 31/01/2024

Clinical situation

Category	Description
Indication	For active immunisation of individuals who are deemed to be at risk from hepatitis A and B viruses.
Inclusion criteria	Adults and children over 1 year old who: • intend to travel to or reside in countries where hepatitis A and B vaccination is currently recommended for travel in accordance with national recommendations issued by TRAVAX **www.travax.nhs.uk/destinations/** the risk of exposure should be determined after careful risk assessment of an individual's itinerary, duration of stay, planned activities and medical history. Valid consent has been given to receive the vaccine.
Exclusion criteria	Individuals for whom no valid consent has been received. Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of any hepatitis A or hepatitis B vaccine or to any components of the vaccines, these may include neomycin (refer to relevant SPC) • 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 • require solely hepatitis A vaccination for overseas travel purposes • previous confirmed hepatitis B infection • previous confirmed hepatitis A infection • are HIV positive. Seek specialist advice. • have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions/need for further advice/ circumstances when further advice should be sought from a	The Green Book advises there are very few individuals who cannot receive hepatitis A and hepatitis B containing vaccines. When there is doubt, appropriate advice should be sought from the lead clinician rather than withholding the vaccine. Individuals who are solely at occupational risk of hepatitis A and/or B exposure

Category	Description
doctor	should be referred to their employer's occupational health provider for vaccination. Individuals who have previously commenced a primary course of monovalent hepatitis A or hepatitis B vaccine should ideally continue the course with monovalent vaccines. Individuals who are immunosuppressed may not make a full antibody response. The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear. 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.
Action if excluded	Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in accordance with local procedures. Inform or refer to the lead clinician in charge. Individuals requiring solely hepatitis B or solely hepatitis A vaccination for overseas travel purposes, should be vaccinated with appropriate monovalent vaccines under the relevant PGD. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Individuals who have had a confirmed anaphylactic reaction to a previous dose of a hepatitis A or B containing vaccine or any components of the vaccines should be referred to a clinician for specialist advice and appropriate management. 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

Category	Description
	as avoiding exposure to blood and bodily fluids).
Action if patient declines	Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine. 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). Document advice given and decision reached. In NHS clinic setting, inform or refer to the lead clinician in charge.

Description of treatment

Category	Description
Name of medicine/Form/strength	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
Route of administration	Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm or the anterolateral area of the thigh muscle in small children. 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** The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer

<table>
<tr><th>Category</th><th>Description</th></tr>
<tr><td></td><td>the vaccine.</td></tr>
<tr><td>Dosage</td><td>Dependent on product, see below</td></tr>
<tr><td>Frequency</td><td>Current UK licensed HepA/B vaccines contain different concentrations of antigen (see table below).
<table>
<tr><th>Vaccine</th><th>Age (licenced 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. When this schedule is applied, a fourth dose is recommended 12 months after the third dose.
• Twinrix® Paediatric: 0.5ml administered at 0, 1 and 6 months
• Ambirix®: 1ml administered at 0 and 6-12 months
For travellers, vaccines should preferably be given at least two weeks before departure but can be given up to the day of departure. If prior to departure there is only time for one dose of Twinrix® Adult or Twinrix® Paediatric to be administered, then to ensure maximum protection against Hepatitis A virus, the use of monovalent hepatitis A vaccine (and therefore monovalent hepatitis B vaccine) is advised. This is due to the reduced dose of Hepatitis A antigen in Twinrix® products.
Reinforcing Immunisation:
<u>Hepatitis A</u>
Until further evidence is available on persistence of protective immunity, a further booster at 25 years is indicated for those at ongoing risk.
<u>Hepatitis B</u></td></tr>
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Category	Description
	Travellers that have received a primary course of hepatitis B immunisation, including children vaccinated according to the routine childhood schedule, do not require a reinforcing dose of hepatitis b containing vaccine.
Duration of treatment	As above
Maximum or minimum treatment period	As above
Quantity to supply/administer	One dose per occasion
▼ black triangle medicines	No
Legal category	Prescription Only Medicine (POM)
Is the use out with the SPC?	Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines or national vaccine incident guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.
Storage requirements	Vaccine should be stored at a temperature of +2° to +8°C. Store in the original packaging to protect from light. Do not freeze. NHS board guidance on Storage and Handling of vaccines should be observed. 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.
Additional information	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. Immunological response may be diminished in those receiving immunosuppressive treatment. There is no evidence of risk from vaccinating pregnant women, or those who are breast-feeding, with inactivated virus or bacterial vaccines or toxoids.

Category	Description
	Vaccination should be considered when the risk of infection is high and benefits are considered to outweigh the risks. Hepatitis A and B vaccines can be given at the same time as other vaccines, including other travel vaccines. 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.

Adverse reactions

Category	Description
Warnings including possible adverse reactions and management of these	For full details/information on possible side effects, refer to the marketing authorisation holder's SPC. Adverse reactions to hepatitis vaccines are usually mild and confined to the first few days after immunisation. The most common reactions are mild, transient pain, redness and swelling at the injection site. Other commonly reported reactions include other injection site reactions (haematoma, pruritus, bruising), general symptoms such as fever, malaise, fatigue, irritability, drowsiness, headache, and gastrointestinal symptoms including nausea, diarrhoea and loss of appetite. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. In the event of severe adverse reaction individual should be advised to seek medical advice.
Reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **http://yellowcard.mhra.gov.uk/** Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.
Advice to patient or	Written information to be given to individuals:

Category	Description
carer including written information	• Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. Individual advice / follow up treatment: • Inform the individual/carer of possible side effects and their management. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **http://yellowcard.mhra.gov.uk/** • When applicable, advise individual/parent/carer when the subsequent dose is due. • 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).
Observation following vaccination	Following immunisation, patients remain under observation in line with NHS board policy.
Follow up	As above
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer vaccines: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council.
Specialist competencies or qualifications	Persons must only work under this PGD where they are competent to do so. All persons operating this PGD: • must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it • must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information, • must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent • must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine • must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy Employer: The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD As a minimum, competence requirements stipulated in the PGD must be

Category	Description
	adhered to.
Continuing education and training	All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

Audit trail

Name	Description
Record/ audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of person that undertook assessment of individual's clinical suitability for vaccine • name of person that administered the vaccine • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • batch number • where possible 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 under PGD Records should be kept in line with local procedures. Local policy should be followed to encourage information sharing with the individual's General Practice. All records should be clear, legible and contemporaneous and in an easily retrievable format.

Additional references

Name	Description
Additional references	Immunisation against Infectious Disease [Green Book] **https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book** Immunisation against Infectious Disease [Green Book] chapters 17 and 18 **Immunisation against infectious disease - Chapter 17 - Hepatitis A (publishing.service.gov.uk)** **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/628602/Greenbook_chapter__18.pdf** Current edition of British National Formulary. Marketing authorisation holder's Summary of Product Characteristics. Professional Guidance on the Administration of Medicines in Healthcare Settings 2019 **https://www.rpharms.com/Portals/0/RPS document library/Open access/Professional standards/SSHM Admin/Admin Meds prof guidance.pdf/ver=2019-01-23-145026-567** Professional Guidance on the Safe and Secure Handling of Medicines **https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines** PHE hepatitis A and B Vaccine Patient Group Direction (PGD) – V2 NHSGGC hepatitis A and B vaccine PGD ref no: 2019/1990

PGD for administration of hepatitis A and B vaccine for travel indications v1.0 Valid from: 01/02/2022 Expiry: 31/01/2024 - authorisation

Practitioner

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's summary of product characteristics for all vaccines administered in accordance with this PGD.

By signing this Patient Group Direction you are indicating that you agree to its contents and that you will work within it. I agree to administer the hepatitis A and B vaccine only in accordance with this PGD.

Name of professional	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 **NHS Borders** for the above named health care professionals who have signed the PGD to work under it.

Lead clinician for the service area

Name ……..

Signature ……..

Date ……

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation. This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.