This patient group direction (PGD) must only be used by registered health 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.

Patient Group Direction (PGD)

For the administration of

Hepatitis A Virus (inactivated) Vaccine (adsorbed)

By registered health care professionals for

individuals considered at high risk of exposure to Hepatitis A or Post Exposure to Hepatitis A Virus in accordance with national recommendations

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 86

Change history (on next page)

1. Change history

Version number	Change details	Date
V01.00	New PHE Hepatitis A vaccine PGD	12/10/2017
V02.00	PHE Hepatitis A vaccine PGD amended to: • include additional healthcare practitioners in Section 3 • refer to vaccine incident guidelines in off-label and storage sections • remove reference to the 'PHE hepatitis A vaccination temporary recommendations' and associated clinical recommendations for times of vaccine supply shortages • 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	12/09/2019
V03.00	PHE Hepatitis A vaccine PGD amended to: • insert missing amended paragraph into 'Additional information' section, relating to the hyperlink from the inclusion criteria for MSM	04/10/2019
V04.00	PHE Hepatitis A vaccine PGD amended to include: • phenylalanine content in Avaxim® vaccine and action to be taken • booster dosing delays still provide protection • minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates	08/10/2021

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy • Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises Additionally practitioners: • 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 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).
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals against hepatitis A infection in accordance with national recommendations including: • Chapter 7 and Chapter 17 of Immunisation Against Infectious Disease: "The Green Book" • NaTHNaC - Hepatitis A (travelhealthpro.org.uk) recommendations for hepatitis A vaccination for travel • Public health control and management of hepatitis A guidance
Inclusion criteria	Adults and children over 1 year old who: • intend to travel, where hepatitis A vaccination is currently recommended for travel by NaTHNaC (see the Travel Health Pro website for country-specific advice on hepatitis A vaccine recommendations) • are at risk of hepatitis A infection because of their sexual behaviour, including men who have sex with men (MSM), see Additional information section • are people who inject drugs (PWID) • are haemophiliac • have chronic liver disease (including alcoholic cirrhosis, chronic hepatitis B, chronic hepatitis C, autoimmune hepatitis, primary biliary cirrhosis) Adults and children from 2 months old who: • are recommended hepatitis A vaccine in accordance with Public health control and management of hepatitis A guidance
Criteria for exclusion[1]	Individuals for whom valid consent, or 'best-interests' decision in accordance with the current Isle of Man legisation, has not been obtained (for further information on consent see Chapter 2 of 'The Green Book'). The Patient information leaflet (PIL) for the vaccine to be used should be available to inform consent. • Individuals who: • are under one year of age, with the exception of those over 2 months of age requiring vaccination in accordance with Public health control and management of hepatitis A guidance • have had a confirmed anaphylactic reaction to a previous dose of hepatitis A vaccine or to any component of the vaccine (including trace components from the manufacturing process which may include formaldehyde, neomycin, ethanol, phenylalanine (see Cautions), polymixin B, egg products or chicken protein see SPCs) • are at increased risk of hepatitis A infection because of their occupation • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

[1] 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

Cautions (including any relevant action to be taken)	• VAQTA®, and VAQTA® Paediatric, syringe plunger stopper and tip cap contain dry natural latex rubber that may cause allergic reactions. As a precaution, if an individual has a history of severe (anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain latex should not be administered, unless the benefit of vaccination outweighs the risk of an allergic reaction to the vaccine. If possible, an alternative latex-free vaccine should be administered (such as AVAXIM® or Havrix®) • Individuals who are immunosuppressed or have HIV infection may not make a full antibody response and revaccination on cessation of treatment/recovery may be required. This should be discussed with the appropriate/relevant specialist • Avaxim® vaccine contains 10 microgram phenylalanine in each 0.5 ml dose, which is equivalent to 0.17 microgram/kg for a 60 kg person. Phenylalanine may be harmful for individuals with phenylketonuria (PKU). The amount in the vaccine is unlikely to adversely affect individuals with PKU, but they should be advised Avaxim® vaccine contains 10 micrograms of phenylalanine. These individuals will be well versed as to the amounts they can tolerate in their diet. If available offer an alternative vaccine. Havrix® Monodose® also has trace amino acids, so VAQTA® would be the preferred option. Alternatively, seek advice from the specialist endocrinologist/metabolic physician looking after the individual with PKU to confirm they are content for them to have Avaxim® • 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
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded *(continued)*	• Patient should be referred to a more experienced clinical practitioner for further assessment • Individuals under one year of age are not recommended pre-exposure hepatitis A vaccination. Individuals from 2 months of age may be considered for immunisation in accordance with Public health control and management of hepatitis A. Where vaccine is not recommended (and even when it is), the importance of stringent hygiene measures should be reinforced • Individuals who have had a confirmed anaphylactic reaction to a previous dose of hepatitis A 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 hepatitis A exposure should be referred to their employer's occupational health provider for vaccination

Action to be taken if patient excluded	• 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
Action to be taken if patient 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/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

8. Details of the medicine

Name, form and strength of medicine	Hepatitis A (inactivated) vaccine (adsorbed), either: • **Havrix® Monodose®** vaccine, hepatitis A virus1440 ELISA units in a pre-filled syringe or vial • **Havrix® Junior Monodose®** vaccine, hepatitis A virus 720 ELISA units in a pre-filled syringe or vial • **AVAXIM®**, hepatitis A virus, (GBM strain) 160 U*, suspension for injection in a pre-filled syringe • **VAQTA® Adult**, hepatitis A virus (strain CR 326F) 50 U* suspension for injection in a pre-filled syringe or vial • **VAQTA® Paediatric**, hepatitis A virus (strain CR 326F) 25 U* suspension for injection in a pre-filled syringe or vial *In the absence of an international standardised reference, the antigen content is expressed using an in-house method of the manufacturer An appropriate vaccine product should be selected for the patient see Dose and frequency of administration section
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No

<table>
<tr><td>Indicate any off-label use (if relevant)</td><td>

Hepatitis A vaccine may be administered off-label to infant hepatitis A contacts from 2 months of age in accordance with Public health control and management of hepatitis A guidance
Administration of Havrix® Monodose or Havrix® Junior Monodose® by deep subcutaneous injection to patients with a bleeding disorder is off-label administration but is in line with advice in Chapter 4 and Chapter 17 of 'The Green Book'. Licensed administration of another brand of hepatitis vaccine where available may be considered as an alternative
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 PHE Vaccine Incident Guidance . 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 consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence

</td></tr>
<tr><td>Route/method of administration</td><td>

Administer by intramuscular injection into the deltoid region of the upper arm. In small infants the anterolateral thigh may be used. The buttock should not be used because vaccine efficacy may be reduced

</td></tr>
<tr><td>Dose and frequency (continued)</td><td>
Current UK licensed hepatitis A vaccines contain different concentrations of antigen per millilitre (see table below). The choice of vaccine and dose used should be guided by the individual's age, immunocompetence and dose recommendations in the vaccine manufacturer's SPC:
<table>
<tr><th>Vaccine</th><th>Age (licenced use)</th><th>Dose</th><th>Volume</th></tr>
<tr><td>Havrix Monodose®</td><td>16 years or over</td><td>1440 ELISA units</td><td>1.0ml</td></tr>
<tr><td>Havrix® Junior Monodose®</td><td>One to 15 years</td><td>720 ELISA units</td><td>0.5ml</td></tr>
<tr><td>AVAXIM®</td><td>16 years or over</td><td>160 antigen units*</td><td>0.5ml</td></tr>
<tr><td>VAQTA® Adult</td><td>18 years of age and older</td><td>50 units*</td><td>1ml</td></tr>
<tr><td>VAQTA® Paediatric</td><td>One to 17 years</td><td>25 units*</td><td>0.5ml</td></tr>
<tr><td colspan="4">*in the absence of an international standardised reference, the antigen content is expressed using an in-house method of the manufacturer</td></tr>
</table>
Primary course:

single dose (see table above).
Vaccination should ideally occur at least 2 weeks prior to possible exposure to infection with hepatitis A.
For travellers, vaccine should preferably be given at least two weeks before departure, but can be given up to the day of departure

</td></tr>
</table>

Dose and frequency *(continued)*	**Reinforcing immunisation:** • for those who require long-term, or subsequent, protection against infection caused by hepatitis A virus a single reinforcing dose (see table above) should be given leaving a minimum interval of 6-12 months after the first dose. Studies have shown successful boosting can occur even when the second dose is delayed for several years, so a course does not need to be re-started • Hepatitis A containing vaccines may be used interchangeably, as appropriate, to complete a course • Until further evidence is available on persistence of protective immunity, a further booster at 25 years is indicated for those at ongoing risk
Quantity to be administered and/or supplied	Dose of 0.5ml or 1.0ml per an administration depending on the age of the individual and vaccine product used, see Dose and frequency
Maximum or minimum treatment period	Dependent of vaccine schedule, see Dose and frequency.
Storage	• Store at between +2°C to +8°C • Store in original packaging in order to protect from light • Do not freeze Stability data indicate that Havrix® Monodose® and Havrix® Junior Monodose® vaccine is stable at temperatures up to 25°C for 3 days. These data are intended to guide healthcare professionals in case of temporary temperature excursion only. This PGD may be used to administer vaccine that has not exceeded these stability data parameters. 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 PHE Vaccine Incident Guidance or any subsequent UKHSA update

Adverse effects	• Adverse reactions to hepatitis A vaccines are usually mild and confined to the first few days after immunisation. The most common reactions are mild, transient soreness, erythema and induration at the injection site. A small, painless nodule may form at the injection site; this usually disappears and is of no consequence • Other commonly reported reactions to hepatitis A vaccination include • general symptoms such as fever, malaise, fatigue, irritability, drowsiness, headache, myalgia, arthralgia and gastrointestinal symptoms including nausea, vomiting, diarrhoea, abdominal pain and loss of appetite • Hypersensitivity reactions and anaphylaxis can occur but are very rare • A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Records to be kept	• The administration of any medication given under a PGD must be recorded within the patient's medical records • See Appendix C for more information.

9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request
Follow-up advice to be given to patient or carer	• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately • Inform the individual/parent/carer of possible side effects and their management. • The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction • When applicable, advise the individual/parent/carer when the subsequent dose is due • When administration is postponed advise the individual/parent/carer when to return for vaccination • Advise the individual/parent/carer of preventative measures to reduce exposure to hepatitis A including careful attention to food and water hygiene and scrupulous hand washing

10. Appendix A

References
Product • Immunisation Against Infectious Disease: The Green Book Chapter 4, updated June 2012, Chapter 7, updated 29 September 2016, and Chapter 17, updated 04 December 2013. https://www.gov.uk/government/collections/immunisation-against- infectious-disease-the-green-book • Summary of Product Characteristic for AVAXIM®, Sanofi Pasteur. Last updated 01 October 2019. https://www.medicines.org.uk/emc/medicine/6206 • Summary of Product Characteristic for Havrix® Junior Monodose®, GlaxoSmithKline UK. Last updated 9 Dec 2016. https://www.medicines.org.uk/emc/medicine/2040 • Summary of Product Characteristic for Havrix® Monodose®, GlaxoSmithKline UK. Last updated 9 Dec 2016. https://www.medicines.org.uk/emc/medicine/2041 • Summary of Product Characteristic for VAQTA® Paediatric, MSD Ltd. Last updated 03 Feb 2017. https://www.medicines.org.uk/emc/product/1397/smpc • Summary of Product Characteristic for VAQTA® Adult, MSD Ltd. Last updated 03 Feb 2017. https://www.medicines.org.uk/emc/medicine/6210 • NaTHNaC recommendations for hepatitis A vaccination for travel. Accessed 12 July 2019. https://travelhealthpro.org.uk/news-topic/16/hepatitis-a • Public health control and management of hepatitis A guidance. Public Health England. Published June 2017. https://www.gov.uk/government/publications/hepatitis-a-infection-prevention-and-control-guidance **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. 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 • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident- guidance-responding-to-vaccine-errors

11. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

12. Appendix C

Route/method of administration	• 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 • The suspension for injection may sediment during storage. Shake the vaccine well before administration to obtain a slightly opaque, white suspension • The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine • The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk
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 regulations and guidance in the technical memorandum 07-01 : Safe management of healthcare waste (Department of Health, 2013)
Drug interacts	• 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 is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Records to be kept *(continued)*	Record: • 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

Records to be kept	immunisation • details of any adverse drug reactions and actions taken • supplied via PGD • Records should be signed and dated (or a password-controlled immuniser's record 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/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
Special considerations/ additional information	• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination • Immunisation is recommended for MSM and they should also be informed about the risks of hepatitis A, and about the need to maintain high standards of personal hygiene during sex • There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated vaccines. Since hepatitis A 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 • Hepatitis A vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis B, hepatitis C and hepatitis E viruses