Public Health England

NHS England

Yorkshire and the Humber

PATIENT GROUP DIRECTION (PGD)

Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccine for injection
(ViATIM®, Hepatyrix®)

For the administration of Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccine for injection to eligible patients in line with national guidance by nurses currently registered with the Nursing and Midwifery Council (NMC) in organisations commissioned by or on behalf of NHS England - North (Yorkshire and the Humber).

Reference:	Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccine for injection (ViATIM®, Hepatyrix®)
Version no:	V1
Valid from:	1st January 2016
Review date:	September 2018
Expiry date:	31st December 2018

The PGD has been authorised following NHS England's governance processes so that it meets the legal requirements for a PGD. Each provider organisation using this PGD should formally adopt it via a signature from the provider's governance lead or lead practitioner.

Practitioners intending to work under the PGD must be individually authorised by their/the designated manager, under the current version of this PGD before working according to it. Each practitioner is professionally accountable for ensuring they have undergone appropriate training and are competent and understand the contents of this PGD and the requirements of the individual vaccine programme, including route of administration, contra-indications etc.

1. Clinical condition or situation to which the direction applies

Indication	Immunisation against Hepatitis A infection and typhoid fever
Objective of programme	The objective of the immunisation programme is to provide protection to individuals at risk of typhoid fever and hepatitis A.
Criteria for inclusion	Individuals aged 16 years and over (15 years and over for Hepatyrix) who are in one of the groups recommended to receive pre-exposure vaccination against Hepatitis A infection and typhoid fever as follows: • Travellers to areas of high or intermediate prevalence of hepatitis A • Travellers visiting typhoid-endemic countries, whose planned activities put them at higher risk; • Travellers to endemic areas with frequent and/or prolonged exposure to conditions where sanitation and food hygiene are likely to be poor. Information on endemnicity is available from NaTHNaC country information pages: http://www.nathnac.org/ds/map_world.aspx
Criteria for Exclusion	• Patient does not meet inclusion criteria • Consent not given/ obtained. • Children under 16 years (Viatim®) and 15 years old (Hepatyrix®). • A confirmed anaphylactic reaction to a previous dose of any component of the vaccine. • A severe general or local reaction to a previous dose of any component of this vaccine • A confirmed anaphylactic reaction to latex • Acute severe febrile illness (having a minor illness without a fever (e.g. a cold) is not a reason to delay immunisation). • History of hypersensitivity to neomycin, traces of which may be present from the manufacturing process. • Individuals who are at increased risk of typhoid and/or hepatitis A because of their occupation. • Pregnancy and breast feeding. Details of excipients may be found in the SPC (see reference to national/ local policies or guidelines').
Action to be taken if excluded	• Consider referring to medical practitioner • For acute severe febrile illnesses advise when the vaccine may be given and arrange a further appointment if needed. • For severe general or local reactions refer to GP who may wish to discuss further with the Consultant in Communicable Disease Control (CCDC) – contact details below. • For confirmed anaphylactic reaction to latex, undertake a risk assessment and refer to GP, who may wish to discuss further with the CCDC (contact details below). Further information is also available in Chapter 6 of Immunisation against Infectious Disease (The Green Book): https://www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6 • Individuals requiring immunisation for occupational reasons should be referred to their GP or employer; • For pregnancy and breast feeding, seek medical advice regarding the risk and benefits and give under patient specific direction (PSD), where

	indicated. • Document exclusions or deferrals in clinical record. The CCDC may be contacted at the local Public Health England Health Protection Team: Bassetlaw - 0344 2254524 South Yorkshire - 0114 3211177 West Yorkshire – 0113 3860300 North Yorkshire and the Humber – Contact the Screening and Immunisation Coordinator for your CCG
Action if patient or carer declines treatment/vaccination	• Advise about the protective effects of the vaccine and the risk of infection and disease complications. • Inform or refer to medical practitioner if patient declines treatment. (For non GP practice personnel – ask patient/carer permission first) • Document refusal and reason if possible in clinical records.
Reference to National / Local policies or Guidelines	Typhoid chapter 33: immunisation against infectious disease – the Green Book'. <accessed 21/10/2015> https://www.gov.uk/government/publications/typhoid-the-green-book-chapter-33 Hepatitis A chapter 17: immunisation against infectious disease – the Green Book'. <accessed 21/10/2015> https://www.gov.uk/government/publications/hepatitis-a-the-green-book-chapter-17 SPCs for Viatim® and Hepatyrix® < accessed 21/10/2015> http://www.medicines.org.uk/emc/medicine/2537 http://www.medicines.org.uk/emc/medicine/7684 NaTHNaC Health Information Sheets ' http://travelhealthpro.org.uk/diseases-in-brief/
Precautions	• 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. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing signs or symptoms to adverse effects of the vaccine. • 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 • For travellers, care should be taken to prevent exposure to typhoid infection through scrupulous attention to food, water and personal hygiene.

2. Description of Treatment

Name, & formulation of drug	Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccine for injection Available as Hepatyrix; Suspension of -inactivated Hepatitis A virus (HM175 grown in human diploid cells) 1440 ELISA units/ml adsorbed onto aluminium hydroxide, combined with typhoid vaccine containing 25 micrograms/ml virulence polysaccharide antigen of Salmonella typhi. AND Viatim; Suspension of formaldehyde-inactivated Hepatitis A virus (grown in human diploid cells) 160 antigen units/ml adsorbed onto aluminium hydroxide, combined with typhoid vaccine containing 25 micrograms/ml virulence polysaccharide antigen of Salmonella typhi.
Presentation	Hepatyrix 1 ml of suspension in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber). Viatim Dual-chamber pre-filled syringe (type I glass): 0.5 ml of suspension in the chamber closest to the plunger and 0.5 ml of solution in the chamber closest to the needle, with a plunger-stopper (chlorobutyl and bromobutyl rubber elastomer blend), a tip cap (elastomer) and a by-pass stopper (elastomer).
Storage	Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccines should be stored in the original packaging at +2˚C to +8˚C and protected from light. The storage of vaccines must comply with the Public Health England protocol updated March 2014. This can be accessed via the link below: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300304/Protocol_for_ordering__storing_and_handling_vaccines_March_2014.pdf
Legal Status	Prescription Only Medicine (POM)
Black Triangle▼	No
Unlicensed / Off label use	Administration by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in Chapter 4 of “The Green Book”.
Route / method of administration	Shake the vaccine well before use. The contents of the syringe should be inspected visually both before and after shaking for any foreign particulate matter and/or abnormal physical appearance prior to administration. Administer by intramuscular injection into the deltoid muscle. For patients with haemophilia and other bleeding disorders vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding. Firm pressure should be applied to the injection site (without rubbing) for at least two minutes after the injection Hepatyrix but not Viatim is licensed for subcutaneous administration. Do not inject into the buttock as vaccine efficacy is reduced. Under no circumstances should it be given by intravenous or intradermal injection.

	Where more than one vaccine is administered at the same time, the vaccines should be given at a separate site, preferably in a different limb. If more than one vaccine is given in the same limb, they should be given at least 2.5cm apart. The sites at which each vaccine was given should be noted in the individual's health records
Dose	1ml
Frequency of administration	Primary course: single dose. Vaccination should occur at least 2 weeks prior to exposure to infection with hepatitis A and typhoid. Reinforcing immunisation: • In order to provide long-term protection against infection caused by the hepatitis A virus, a second dose (booster) of an inactivated hepatitis A vaccine should be given. • Subjects who remain at risk of typhoid fever should be revaccinated using a single dose of Vi polysaccharide vaccine every 3 years. • Hepatyrix® or ViATIM® may also be given as a single dose for booster vaccination between 6 and 12 months following primary immunisation with an inactivated single hepatitis A vaccine to subjects who now also require protection against typhoid.
Total doses	Single dose of 1ml
Disposal	Equipment used for Viatim®/Hepatyrix® immunisation, including used syringes, should be disposed of at the end of a session by sealing in a UN approved 'sharps' container, with yellow coloured lid according to local sharps and/or waste management policy and HTM 07-01 the Safe Management of Healthcare Waste (Department of Health, 2013). https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste
Drug Interactions	Vaccines must not be mixed with other vaccines/medicines in the same syringe.
Potential Adverse Reactions	Some reactions to vaccination are predictable (although it is not possible to predict who will be affected and to what extent), most are mild and resolve quickly, however some people will have a more severe reaction to the vaccine administered. **Commonly reported symptoms** • Pain, discomfort, redness or swelling at the injection site • Low grade fever, headache, malaise, fatigue, shivering, aching muscles and joint pains • The above symptoms usually disappear within one to two days without treatment Please refer to the product's SPC for other adverse events. Advice is available from: • The screening and immunisation coordinator within the Screening and Immunisation Team

	• The Consultant in Communicable Disease Control (CCDC) at your local Public Health England Health Protection Team Bassetlaw 0344 2254524 South Yorkshire 0114 3211177 West Yorkshire 0113 3860300 North Yorkshire and the Humber Contact the Screening and Immunisation Coordinator for your CCG
Reporting procedure of adverse reactions	All vaccine related incidents (including adverse events, administration errors, vaccine quality, device defects etc.) must be reported to the Screening and Immunisation Team at NHS England via england.sybsit@nhs.net and to the MHRA Information on what to report can be found in the Green Book (Chapter 9) https://www.gov.uk/government/publications/surveillance-and-monitoring-for-vaccine-safety-the-green-book-chapter-9 or via the MHRA: https://www.gov.uk/the-yellow-card-scheme-guidance-for-healthcare-professionals The yellow card scheme can now be used to report any of the following incidents/concerns. Incidents should be reported via http://www.gov.uk/yellowcard • Suspected adverse drug reactions • Defective Vaccines e.g. errors in packaging, labelling, contamination etc • Defective Medical Devices e.g. syringes, needles, vials, ampoules etc https://www.gov.uk/drug-safety-update/yellow-card-extended-to-include-devices-counterfeits-and-defective-medicines
Advice to patient / carer including written information and follow up treatment	• The purpose and benefits of immunisation • Possible side effects and their management (including normal reactions to the injection e.g. sore arm) • Advise to seek urgent medical attention if the patient develops swelling (other than localised), rash or breathlessness • Issue vaccine manufacturer's Patient Information Leaflet (PIL). • If treatment is deferred, explain why and arrange a new appointment • Whilst paracetamol and ibuprofen can lower the duration of fever and reduce distress, there is no evidence that they prevent febrile convulsions. It is recommended that these drugs are not routinely used to prevent fever following vaccination as there is some evidence that prophylactic administration of antipyretic drugs around the time of vaccination may lower antibody responses to some vaccines and/or may mask other reasons for/causes of the temperature and delay diagnosis. The use of paracetamol prophylactically should only be used on the specific recommendation of the JCVI. • Give advice re: discomfort, swelling, fever, aching muscles and joint pains: - usually disappear within one to two days, but can treat with self-administration of paracetamol or ibuprofen if required. NB Ibuprofen should be avoided in pregnancy. Patients/carers may be referred to the local community pharmacist for further advice. Health professionals can refer to the British National Formulary or British National Formulary for children as applicable

	• Dosage and frequency of follow-up treatment should be as per manufacturer's instructions.
Special considerations and additional information	• As with most vaccines, anaphylactic reactions are extremely rare. An anaphylaxis pack which enables immediate access to epinephrine (adrenaline) 1 in 1000 injection and access to a telephone must always be readily available in case of an anaphylactic event following the administration of the vaccine. A PGD for adrenaline 1 in 1000 injection is not required as it is exempt from the prescription-only medicine requirement when administered for the purpose of saving a life in an emergency.
Records	In all cases, regardless of the setting where the vaccine is administered, vaccinators must ensure that records are kept in line with NMC Record Keeping Guidance (2009) and other professional codes of practice as applicable. Documentation includes the Personal Held Child Record (PHCR – red book), other hand held records (e.g. maternity), GP records, computerised records and data collection for Child Health Information Services (CHIS), where applicable. The patient's clinical record must be updated as soon after vaccination as is reasonably practicable (ideally within one working day) as delays may result in clinical error. For providers outside of general practice and who therefore do not hold the patient's clinical record, notification of vaccination should ideally be reported to the practice within one working day but must be in accordance with any local Service Specification. The record should include: • Assessment of the patient's need in relation to the intervention • Patient's name, address, date of birth and GP with whom the patient is registered. • Dose and form of vaccine administered • Site and route of administration • Brand, batch number and expiry date of vaccine • Date given • Name of the practitioner administering the vaccine • Consent – following local guidelines • Advice given to the patient/carer • Advice given if excluded or declines treatment • For any contraindications/exclusions the course of action taken and the outcome. • Record how the patient's central record or GP surgery record will be updated, where applicable • Details of any adverse drug reactions and actions taken • Record that the supply was made via PGD Medications given under a PGD must be appropriately READ coded in the patients clinical record. The READ codes to be used are: • SystmOne - XaQA7 • Emis – 8BMN Entries made in any record should ensure the practitioner delivering the care is clearly identifiable. Clinical records must be kept for at least 8 years following completion of treatment. In patients aged under 17 years, clinical records must be kept until the patient's 25th birthday, or for 8 years following a child's death.

3. Characteristics of Staff

Qualifications required	Registered Nurse, currently registered with the NMC, or other registered healthcare professional contracted to or on behalf of the NHS England SYB Area Team and who has completed a relevant immunisation training programme recognised by their employing organisation. This should ideally be in accordance with the HPA national standards for immunisation training. http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1196942164323
Additional requirements	All health professionals responsible for immunisation must have appropriate training for resuscitation of a patient with anaphylaxis to prevent disability and loss of life. They must be familiar with their employing organisations' policy on the management of anaphylaxis for adults and children. If the employing organisation does not have such a policy/protocol then vaccination under this PGD is not permitted. Knowledge of and access to: • Resuscitation Council (UK) (2008): Emergency treatment of anaphylactic reactions http://www.resus.org.uk/pages/reaction.htm • NICE (2011): Clinical Guideline 134. Anaphylaxis http://guidance.nice.org.uk/CG134 • Summary of Product Characteristics (SPC) for Hepatyrix and Viatim http://www.medicines.org.uk/emc/medicine/7684 http://www.medicines.org.uk/emc/medicine/2537 • Patient information leaflet (PIL) for Hepatyrix and Viatim http://www.medicines.org.uk/emc/medicine/17386 http://www.medicines.org.uk/emc/medicine/9091 • NMC Record Keeping Guidance (Nurses and Midwives) • NMC The Code - Professional standards of practice and behaviour for nurses and midwives) • NMC Standards for Medicines Management (Nurses and Midwives) • Relevant professional code of practice • Immunisation against infectious disease (*The Green Book*), relevant updates and compliance with its recommendations (now only available electronically) https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book • CCG or individual organisations' Consent Policy • NICE (2013): Medicines Practice Guidelines 2. Patient Group Directions – Section 2.5 Using patient group directions http://www.nice.org.uk/guidance/mpg2/chapter/2-recommendations#/using-patient-group-directions
Continued training requirements	○ Maintenance of own level of updating with evidence of continued professional development as appropriate and in line with PREP (Post Registration Education and Practice) or other professional registration requirements. ○ Annual vaccination and immunisation updates are recommended for all staff involved in immunisation in line with national guidance. ○ Annual updates on resuscitation skills for adults and children (including defibrillation training where defibrillator is available) and the management of anaphylaxis within the community.

4. PGD Development Team

Developed & Produced by:	Name of Developer, Job Title and Employing Organisation	Signature	Date
Christopher Ranson Senior Pharmacist	Senior Pharmacist Harrogate and Rural district CCG		18 Dec 2015
Doctor (Lead Author)	Graham Sutton – CCDC and Vaccination and Immunisation Lead PHE Yorkshire and the Humber Centre		19 Nov 2015
Senior Registered Nurse	Kathy Wakefield – PHE Screening and Immunisation Manager (on behalf of NHS England North – Yorkshire and the Humber)		10.12.15

Acknowledgements (this may include representatives from CCG Medicine Management Teams who have contributed via consultation)

Name	Designation

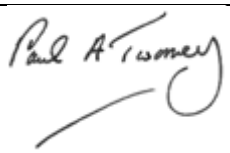
4.1 Version Control

Version	Change
V1	**Complete review in line with new process for Yorkshire and the Humber**

5. Organisational Authorisations

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

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met.

Approved by:	***Name and Job Title***	***Signature***	***Date***
NHS England	Paul Twomey Medical Director (Yorkshire and the Humber)		22.12.15

Approved by NHS England North (Yorkshire and the Humber) Senior Management Team	Date:

Adoption for use by the provider organization is recommended as part of good clinical governance (to be determined locally if relevant i.e may not be applicable if independent single pharmacy)

Name of Provider Organisation	Name of Person accepting on behalf of provider organisation (please print)	Designation of Person accepting on behalf of provider organisation (please print)	Signature of Person accepting on behalf of provider organisation	Date

Public Health England

NHS England

Patient Group Direction for the administration of Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccine for injection (ViATIM, Hepatyrix)

Individual Practitioner Authorisation

Organisations must complete an Individual Practitioner Authorisation sheet for each person planning to practice under this PGD. You do not need to return signed sheets to the Area Team but you should retain copies as part of your organisation's internal governance arrangements. You may wish to retain a copy in the individual's personal file.

Practitioner

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PATIENT GROUP DIRECTIONS 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.

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

Signed…….. Date…….....

Name (Print) ……..……

Designation……

Authorising Manager

Designated Manager to give authorisation * for the Health Care Professional named above and who has signed the PGD

Signed…….. Date…….....

Name (Print) ……...

Designation……

On behalf of: Name of organisation …….

***Note to Authorising Manager**

By signing about you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so.

You must give this signed PGD to each Authorised Practitioner as it shows their authorisation to use the PGD.