

Yorkshire and the Humber

PATIENT GROUP DIRECTION (PGD)

**Typhoid Vi Polysaccharide Vaccine for Injection
(Typherix®, Typhim Vi®)**

For the administration of **Typhoid Vi polysaccharide vaccine for injection** to eligible patients in line with national guidance by nurses currently registered with the Nursing and Midwifery Council (NMC) and/or other registered healthcare professionals e.g. pharmacists, in organisations commissioned by or on behalf of NHS England.

Reference:	Typhoid Vi Polysaccharide Vaccine for Injection (Typherix®, Typhim Vi®)
Version no:	v2 (Final)
Valid from:	1 st September 2015
Review date:	March 2017
Expiry date:	31 st August 2017

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 typhoid fever
Objective of programme	The objective of the immunisation programme is to provide protection to individuals at risk of typhoid fever
Criteria for inclusion	<p>Individuals aged 2 years and over in the following groups:</p> <ul style="list-style-type: none"> • 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; <p>Information on endemnicity is available from NaTHNaC country information pages: http://www.nathnac.org/ds/map_world.aspx</p>
Criteria for Exclusion	<ul style="list-style-type: none"> • Patient does not meet inclusion criteria • Consent not given/obtained • 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 the vaccine • A confirmed anaphylactic reaction to latex • Typhim Vi® may contain trace residues of formaldehyde used in the manufacture and should not be given to patients with a confirmed anaphylactic or severe general or local reaction to this; Typherix® may be used in these patients • Acute severe febrile illness (having a minor illness without a fever, e.g. a cold, is not a reason to delay immunisation) • Individuals who are at increased risk of typhoid because of their occupation • Pregnancy and breast feeding <p>Details of excipients may be found in the SPC (see 'Reference to National / Local policies or Guidelines').</p> <p>Severe reaction to a previous dose of non-Vi typhoid vaccine does not contraindicate the subsequent use of a Vi vaccine.</p>
Action to be taken if excluded	<ul style="list-style-type: none"> • 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/uploads/system/uploads/attachment_data/file/147824/Green-Book-Chapter-6-v2_0.pdf • 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



	<p>indicated.</p> <ul style="list-style-type: none"> • Children between the age of 12 months and 2 years at a high risk of typhoid infection should be referred to a medical practitioner for assessment and give under a PSD, where indicated. • Document exclusions or deferrals in clinical record <p>The CCDC may be contacted at the local Public Health England Health Protection Team:</p> <p>Bassetlaw - 0344 2254524 South Yorkshire - 0114 3211177 West Yorkshire – 0113 3860300 North Yorkshire and the Humber – 01904 687100</p>
<p>Action if patient or carer declines treatment/vaccination</p>	<ul style="list-style-type: none"> • 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.
<p>Reference to National / Local policies or Guidelines</p>	<p>Typhoid chapter 33: 'Immunisation against infectious disease - the Green Book'. PHE updated October 2014. >> accessed 17/07/15<< https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/366867/Green_Book_Chapter_33_v1_3.pdf</p> <p>SPCs for Typherix®, Typhim Vi® >>accessed 17/07/15<< http://www.medicines.org.uk/emc/medicine/2063/SPC/Typherix http://www.medicines.org.uk/emc/medicine/6186/SPC/TYPHIM+Vi</p> <p>GPC Guidance for GPs: Focus on Vaccines and Immunisation. BMA June 2014 >>accessed 17/07/15<< http://bma.org.uk/practical-support-at-work/gp-practices/focus-vaccinations</p> <p>NaTHNaC Health Information Sheets 'Typhoid and paratyphoid' >>accessed 17/07/15<< http://www.nathnac.org/travel/factsheets/typhoid_paratyphoid.htm</p>
<p>Precautions</p>	<ul style="list-style-type: none"> • 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. • The vaccine does not prevent against infection with paratyphoid. <p>Pregnancy and breast feeding: Although there is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids, there is a lack of clinical studies with typhoid Vi polysaccharide</p>

	vaccine. Immunisation with should not be withheld where there is a high risk of infection but this should be administered under a patient specific direction.
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2. Description of Treatment

Name, strength & formulation of drug	<p>Typhoid Vi polysaccharide vaccine for injection</p> <p>Available as Typherix®, Typhim Vi® 50micrograms/ml virulence polysaccharide antigen of Salmonella typhi (Ty2 strain).</p> <p>Note: this PGD does not cover administration of the live oral typhoid vaccine Vivotif®</p>
Presentation	<p>Typherix® 0.5 ml (25mcg) solution single dose in pre-filled syringe (Type I glass) with a plunger stopper (elastomer rubber butyl)</p> <p>Typhim Vi® 0.5 ml (25mcg) solution single dose in pre-filled syringe (Type I glass) with plunger (chlorobromobutyl, bromobutyl or chlorobutyl elastomer) and tip cap (chlorobromobutyl elastomer) with or without needles</p>
Storage	<p>Typhoid Vi polysaccharide vaccines should be stored in the original packaging at +2°C to +8°C and protected from light.</p> <p>The storage of vaccines must comply with the Public Health England protocol updated March 2014: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300304/Protocol_for_ordering_storing_and_handling_vaccines_March_2014.pdf</p>
Legal Status	Prescription Only Medicine (POM)
Black Triangle ▼	No
Unlicensed / Off label use	The PGD is within the marketing authorisation of the products with the exception of the subcutaneous administration of Typherix®, see under 'Route/method of administration'.
Route / method of administration	<p>Shake syringe immediately before use</p> <p>Administer by intramuscular injection into deltoid region or into the antero-lateral part of the thigh.</p> <p>For patients with haemophilia and other bleeding disorders the 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.</p> <p>Typhim Vi® but not Typherix® is licensed for subcutaneous administration.</p> <p>Do not give by intradermal injection</p> <p>Under no circumstances should typhoid Vi vaccines be given intravenously</p> <p>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</p>

	least 2.5cm apart. The sites at which each vaccine was given should be noted in the individual's health records.
Dose	0.5ml (25mcg)
Frequency of administration	<p>Primary course: single dose</p> <p>Vaccination should occur at least 2 weeks prior to potential exposure to infection with Salmonella typhi.</p> <p>Reinforcing immunisation: a single dose of the vaccine should be administered at three-year intervals in adults and children over two years of age who remain at risk from typhoid fever.</p> <p>Individuals who have received other non-Vi typhoid vaccines may receive reinforcing doses of Vi vaccine at three-year intervals as required.</p>
Total doses	As detailed under 'Frequency of administration'
Disposal	<p>Any equipment used for typhoid 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).</p> <p>https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste</p>
Drug Interactions	<p>Vaccines must not be mixed with other vaccines/medicines in the same syringe.</p> <p>Typhoid Vi polysaccharide vaccine can be given at the same time as other vaccines, including travel vaccines. See 'Route/method of administration' for further information.</p>
Potential Adverse Reactions	<p>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.</p> <p>Commonly reported symptoms</p> <ul style="list-style-type: none"> • Pain, discomfort, redness or swelling at the injection site are most commonly reported • Systemic reactions such as low grade fever, headache, malaise, fatigue, shivering, nausea, abdominal pain, aching muscles and joint pains are less frequent <p>The above symptoms usually disappear within one to two days without treatment</p> <p>Please refer to the product's SPC for other adverse events. Advice is available from:</p> <ul style="list-style-type: none"> • Your 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:



	<p>Bassetlaw 0344 2254524 South Yorkshire 0114 3211177 West Yorkshire 0113 3860300 North Yorkshire and the Humber 01904 687100</p>
<p>Reporting procedure of adverse reactions</p>	<p>All vaccine related incidents (including adverse events, administration errors, vaccine quality, device defects etc.) must be reported to the Screening and Immunisation Team based within NHS England.</p> <p>Information on what to report can be found in the Green Book (Chapter 9) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147870/Green-Book-Chapter-9.pdf or via the MHRA: https://www.gov.uk/the-yellow-card-scheme-guidance-for-healthcare-professionals</p> <p>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</p> <ul style="list-style-type: none"> • Suspected adverse drug reactions • Defective vaccines e.g. errors in packaging, labelling, contamination etc • Defective medical devices e.g. syringes, needles, vials, ampoules etc <p>https://www.gov.uk/drug-safety-update/yellow-card-extended-to-include-devices-counterfeits-and-defective-medicines</p>
<p>Advice to patient / carer including written information and follow up treatment</p>	<ul style="list-style-type: none"> • The purpose and benefits of immunisation • For travellers, advise that the vaccine is not completely effective and does not cover paratyphoid or other gastrointestinal infections .Care should be taken to prevent exposure through scrupulous attention to food, water and personal hygiene. • Possible side effects and their management (including normal reactions to the injection e.g. sore arm) • 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 or may mask other reasons for/causes of the temperature and delay diagnosis. Paracetamol should only be given prophylactically when specifically recommended by 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. • Dosage and frequency of follow-up treatment should be as per manufacturer’s instructions. <p>Health professionals can refer to the British National Formulary or British National Formulary for children: https://www.medicinescomplete.com/mc/index.htm</p>



<p>Special considerations and additional information</p>	<ul style="list-style-type: none"> 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. Young children may show a sub-optimal response to polysaccharide antigen vaccines. The typhoid Vi vaccines are licensed from 2 years and above. The JCVI advice is that children between the ages of 12 months and two years may be immunised if the risk of typhoid fever is considered high but this is not covered by the PGD and should be given on a patient specific direction. Immunisation is not recommended for children under one year of age.
<p>Records</p>	<p>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 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. 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.</p> <p>The record should include:</p> <ul style="list-style-type: none"> 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 <p>Medications given under a PGD must be appropriately READ coded in the patients clinical record. The READ codes to be used are:</p> <ul style="list-style-type: none"> SystmOne - Xa QA7 Emis – 8BMN <p>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.</p>



3. Characteristics of Staff

<p>Qualifications required</p>	<p>Registered Nurse, currently registered with the NMC, or other registered healthcare professional, in organisations commissioned by or contracted to NHS England 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.</p> <p>http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1196942164323</p>
<p>Additional requirements</p>	<p>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.</p> <p>Knowledge of and access to:</p> <ul style="list-style-type: none"> • 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 Typherix®, Typhim Vi®: http://www.medicines.org.uk/emc/medicine/2063/SPC/Typherix http://www.medicines.org.uk/emc/medicine/6186/SPC/TYPHIM+Vi • Patient information leaflet (PIL) for Typherix®, Typhim Vi®: http://www.medicines.org.uk/emc/medicine/3153/PIL/Typherix/ http://www.medicines.org.uk/emc/medicine/17387/PIL/TYPHIM++Vi/ • 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 (<i>The Green Book</i>), relevant updates and compliance with its recommendations (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
<p>Continued training requirements</p>	<ul style="list-style-type: none"> ○ 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. ○ 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
Senior Pharmacist	Hilde Storkes Medicines Governance Pharmacist NHS Sheffield CCG;		24 July 2015
Doctor (Lead Author)	Dr Graham Sutton CCDC PHE Yorkshire and the Humber (Vacc and Imm Lead)		24 July 2015
Senior Registered Nurse	Kathy Wakefield – Screening and Immunisation Manager (PHE on behalf of NHS England)		24 July 2015

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

Name	Designation

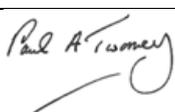
4.1 Version Control

Version	Change
V2	Section 2 (Description of Treatment) – updated information re: booster dose.

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		12 th August 2015



	Humber		
NHS England	Zena Robertson Nurse Director Yorkshire and the Humber		19 August 2015

Adoption for use by the provider organisation (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

**Patient Group Direction for the administration of
Typhoid Vi Polysaccharide Vaccine for Injection (Typherix®, Typhim Vi®)**

Individual Practitioner Authorisation

Organisations must complete an Individual Practitioner Authorisation sheet for each person planning to practice under this PGD. Unless locally required you do not need to return signed sheets to the Screening and Immunisation Team/CCG, however 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.