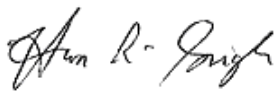
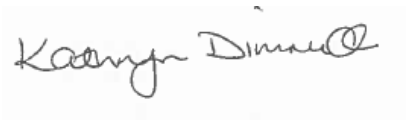
Patient Group Direction (PGD) for the Administration of

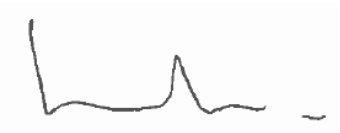
TYPHOID VACCINES (TYPHIM Vi®, TYPHERIX® and VIVOTIF®)

by Registered Professionals to Individuals Accessing NHS Services in Cumbria and North East Sub Region (NHS England North)

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT.

Direction Number: - **NECSAT 2017/004**
Valid from: 1st March 2017
Review date: 1st December 2018
Expiry date: 31st March 2019

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
Medicines Optimisation Pharmacist (Lead Author) (North of England Commissioning Support)	**Hira Singh** *(Senior Pharmacist)*		21/02/17
Transforming Care Quality Manager (NHS England, Cumbria and North East)	**Kathryn Dimmick** *(Senior Nurse)*		21/02/17
Medicines Optimisation Pharmacist (North of England Commissioning Support)	**Marie Thompkins** *(Senior Pharmacist)*		22/02/17
Assistant Medical Director (NHS England, Cumbria and North East)	**Dr James Gossow** *(Senior Doctor)*		27/02/17

This PGD has been approved for use in Cumbria and North East Sub Region (NHS England) by:			
Title	Name	Signature	Date
Interim Medical Director (NHS England Cumbria and North East)	**Dr Jonathan Slade** *(Governance Authorisation)*		28/02/17

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

Immunisation against Typhoid Fever in Adults and Children aged 1 year or over.

Objectives of care

- To prevent infectious disease and promote health. To reduce morbidity & mortality and to eradicate disease.

Inclusion criteria (as per Public Health England (PHE) Green Book Guidance

(Only use those criteria that are specific to your authorised role & competence).
Ensure appropriate consent has been obtained or a best interest decision is in place before commencing any vaccination.
Active immunisation in adults and children aged 1 year & over, who are at risk of contracting typhoid fever. These include: -

- Travellers visiting typhoid-endemic areas whose planned activities put them at higher risk (please check the country information pages www.Nathnac.org and www.travax.nhs.uk).
- Travellers to endemic areas (see above) with frequent and/or prolonged exposure to conditions where sanitation and food hygiene are likely to be poor.
- Children aged 1 to under 2 years old **if the risk of typhoid is very high**, (NB. the response to the vaccine may be suboptimal).

Refer to chapter 33 of the "Green Book" (latest on line version) for full details of inclusion.

Exclusion criteria

General exclusions *(Refer to current Summary of Product Characteristics (SPC) and latest BNF (Appendix 1) for full list of details)***: -**

- No valid consent /best interest decision in place;
- Children under 12mths old. (NB. Vaccine is ineffective, therefore scrupulous hygiene should be observed, seek specialist advice)
- Patient is acutely unwell – (postpone vaccination until recovered. Minor illnesses without fever or systemic upset are not reasons to postpone immunisation).
- Pregnancy (known or suspected) and during lactation;
- Have a confirmed anaphylactic reaction to any ingredient, excipient or component of the vaccine. Practitioners must check SPC.
- Have a confirmed anaphylactic reaction to a previous dose of a typhoid containing vaccine.
- Severe hypersensitivity to any ingredient or component of the vaccine(s) – **(please also refer to precautions section).**

Specific exclusions:

Vivotif capsules

- Children under 6yrs old. During an acute gastrointestinal illness, (vaccination should be postponed until after recovery).
- To persons with congenital or acquired immune deficiency (including those patients receiving immunosuppressive or antimitotic drugs). Also, individuals who are immunosuppressed or are HIV-infected.

Refer to current Summary of Product Characteristics (SPC) / Green Book (current on-line version)/ latest BNF for full list of details

Precautions

- **Hypersensitivity reactions to previous dose of vaccine or component of vaccine:**

  - NB. "Local adverse reactions that generally start within a few hours of the injection are usually mild and self-limiting. Although these are often referred to as 'hypersensitivity reactions', they are not allergic in origin, but may be either due to high titres of antibody or a direct effect of the vaccine product, e.g. endotoxin in whole-cell bacterial vaccines. The occurrence or severity of such local reactions does not contraindicate further doses of immunisation with the same vaccine or vaccines containing the same antigens."

- Immediate access to epinephrine (adrenaline) 1 in 1000 injection. Syringes and needles of suitable size and capacity for dose should be available.
- **Pregnancy and breast feeding:** No data are available on the safety of Vi polysaccharide and Ty21a typhoid vaccines in pregnancy or during lactation. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids (Plotkin and Orenstein, 2004). It is not known if Ty21a vaccine can cause fetal harm when administered to pregnant women or affect reproductive ability. If the risk of typhoid is high, vaccination should be considered. Seek specialist advice.
- **Response to vaccines may be suboptimal** if patient is immunosuppressed because of disease such as HIV, or treatment e.g. chemotherapy, radiation treatment, steroids or other immunosuppressant drugs. Specialist advice may be required. **Please note specific Vivotif exclusions also.**
- **Individuals with immunosuppression and HIV infection** should still be vaccinated according to the schedule. However they may have a sub-optimal immune response to Vi vaccine. The importance of scrupulous attention to personal, food and water hygiene must be emphasised for immunosuppressed persons travelling to endemic areas. Specialist advice may be required.
- **In the event of gastrointestinal illness:**
  Vaccination with the Ty21a vaccine (i.e. Vivotif) should be postponed until after recovery. Ty21a vaccine should not be commenced within 3 days of completing any antibacterial agents, and similarly, antibacterial therapy should not commence within 3 days after the last dose of vaccine.
- **If malaria prophylaxis is also required,** the fixed combination of atovaquone and proguanil can be given concomitantly with Ty21a. Doses of mefloquine and Ty21a should be separated by at least 12 hours. For other anti-malarials, there should be an interval of at least three days between the last dose of Ty21a and the first dose of malaria prophylaxis.

Action if excluded

- There are few individuals who cannot receive typhoid containing vaccines. **When there is doubt or reason for caution, discuss with or refer to clinician/doctor/local communicable disease specialist.**
- Ensure all actions/decisions are documented. / The risk to the individual of not being immunised must be taken into account.
- If postponement due to acute illness, arrange a future date for immunisation.

Circumstances in which further advice should be sought from a doctor and/or specialist

- Patient meeting the exclusion criteria. / Patient requires additional info. in order to decide whether or not to have the vaccination;
- A Best Interest decision is required for an individual who lacks mental capacity to consent. Seek support from lead clinician responsible for individuals care.

Action if vaccination refused

- Refusal should be accepted. Ensure patient/guardian/carer fully understands the risks of declining vaccination.
- Provide advice on personal, food and water hygiene.
- Advise about protective effects of vaccine & the risks of infection and disease complications If postponement due to acute illness, arrange a future date for immunisation
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate

Special Considerations / Additional Information

Typhim Vi: - TYPHIM Vi is a clear, colourless solution. Immunity appears within 2-3 weeks after injection and lasts around 3 years.

Vivotif: - Protection against typhoid fever commences approximately 7-10 days after ingesting the third dose of vaccine.

2. Description of treatment

Name, strength & formulation of drug

Inactivated Typhoid Polysaccharide Vaccines available as: -

- **Typhim Vi** ® (Soln for injection): (Sanofi Pasteur): **0.5ml pre-filled syringe** with plunger. (Clear colourless solution) Each 0.5ml dose contains **25microgramms** of purified Vi capsular polysaccharide of *Salmonella typhi* (Ty2 strain)
- **Typherix** ® (Soln for injection): (GlaxoSmithKline): **0.5ml pre-filled syringe** with plunger stopper. (Clear colourless solution). Each 0.5ml dose contains **25mcg** of Vi polysaccharide of *Salmonella typhi* (Ty2 strain)

Live typhoid vaccine available as:

- **Vivotif** ® (Capsules) (PaxVax Ltd): Enteric coated capsules (3 capsule pack) Each capsule contains *S.typhi* Ty21a not less than 2 x 10^9 viable cells.

Legal Status:

POM –Prescription Only Medicines (Use of Typherix & Typhim Vi between 1 & 2yrs old is off label, but Green Book recommended)

Dosage /Dose range

Typhim Vi:	**2 years old and over:**	**0.5ml (25mcg)**
Typherix:	**2 years old and over:**	**0.5ml (25mcg)**
Vivotif:	**Adults/Children ≥ 6yrs old:**	**Take one capsule on day 0, 2 and day 4**

Children under 2 years of age

Use in this age range is unlicensed but follows Public Health England (PHE) Green Book guidance as follows:

Children between 1 and under 2 years of age should be immunised if the risk of typhoid fever is considered high. This should be done in consultation with the doctor if required.

Typhim Vi:	**1 year to under 2 years of age:**	**0.5ml**
Typherix:	**1 year to under 2 years of age:**	**0.5ml**

Vaccination with Typhim Vi or Typherix should be administered at least **two weeks prior** to risk of exposure to typhoid fever.

(See also updated Typhoid chapter 33, Immunisation against infectious disease – "The Green Book" online version).

Route/Method

Typhim Vi & Typerix: Intra-muscular (IM) injection. Use deep subcutaneous inj. for those with bleeding disorders.

Vivotif: **Oral** (Vivotif capsules should be taken approximately one hour before a meal with a cold or lukewarm drink on alternate days, e.g. days 0, 2 and 4. The vaccine capsule should not be chewed and should be swallowed as soon as possible after placing in the mouth).

Frequency of Administration (refer to PHE Green Book, chapter 33 (online version) for additional details

For Typhim Vi and Typherix: -

- A single dose at 3 yearly intervals if required for travel and who remain at risk from Typhoid fever. (Should be administered at least two weeks before potential exposure to typhoid infection).

For Vivotif: - Travel from a non-endemic area to an area where typhoid fever is endemic, an annual booster consisting of three doses is recommended. Under conditions of repeated or continuous exposure to *S. typhi* protection persists for at least 3 years.

Maximum dose & number of treatments

Maximum single dose: - 0.5ml (Typhim Vi and Typherix)
1 capsule (Vivotif)

Maximum no. of treatments: - Variable (as above)

Follow up treatment

- Booster doses are needed every 3 years on continuous exposure. Refer to "Frequency of Administration" section.

3. Further Aspects of Treatment

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - See manufacturers SPC for full details / current Green Book online Chapter 33
- The vaccine does not protect against paratyphoid fever.

Potential Adverse Effects/ Reactions: - Usually transient and only last a few days after vaccination.

Please be aware of Resuscitation Council Guidelines (October 2015)

	TYPHIM Vi ® (Typhoid polysaccharide vaccine)	**TYPHERIX ®** (Typhoid polysaccharide vaccine)	**VIVOTIF ®** (Oral Capsule)
Very Common & Common Reactions	Mild & transient soreness; swelling, redness and pain at the injection site. Fever, headache, general aches, nausea, vomiting, fatigue & malaise have all been reported during the first 48hrs post vaccination. Itching (Typherix);		Abdominal pain, nausea, diarrhoea, vomiting. Fever, Influenza like illness Headaches, rash
Uncommon	Urticaria (for Typhim Vi)		N/A
Rarely	Anaphylactic reaction, Urticaria (Typherix)		Anaphylaxis, dermatitis, urticaria

This list is not exhaustive. Please also refer to current manufacturers SPC for details of all potential adverse reactions and on line version of the Green Book for detailed information.

Identification and Management of Adverse Reactions

- Patient/ Carer / Guardian requested to report side effects
- Advice on management including anaphylaxis: - Chapter 8 of the Green Book provides detailed advice on managing adverse drug reactions (ADRs) following immunisation, e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor/specialist as appropriate

Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All adverse reactions due to ▼ vaccines should be reported to the MHRA using the yellow card system.
- For established vaccines only report serious adverse reaction. Please refer to www.mhra.gov.uk/yellowcard and the online Green Book - Chapter 9.

  See manufacturers SPC for details of all potential adverse reactions.

Advice to Patient / Carer (verbal or written)

- Explain protection level expected from vaccine. Provide a patient information leaflet and discuss as required.
- Provide advice on & explain potential warnings & side effects and request to report them if they occur.
- Provide advice on management of adverse reactions (see above and manufacturers SPC).
- Explain procedure for dealing with anaphylaxis /severe allergic reactions.
- Explain the "Out of Hours" procedure. Give date of next vaccine if applicable.
- Provide patient with vaccination record card (to include date of next vaccination, completion of course or blood test) if applicable.
- Provide advice on personal, food and water hygiene.
- Complete patient-held vaccination record (where applicable)

Arrangements for Referral to Medical Advice

- Doctor/specialist appointment as and when appropriate. Additional vaccine related advice may also be obtained from Nathnac (http://www.nathnac.org) and Travax (http://www.travax.nhs.uk) websites.

Records

In all cases manual records, computerised records and data collection should include: -

- Patient's name and date of birth;
- Reason vaccination required;
- Date of administration;
- Confirmation that consent has been obtained;
- Dose, site and route of injection;
- Brand name, batch number and expiry date of vaccine;
- Whom administered by and signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications; That side effects have been discussed; Support literature given (if applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.
- Any immunisation/vaccine related incident should be reported to Cumbria and North East Sub Region (NHS England North).

Additional Facilities

- Access to updated online Green Book information; the latest SPC and BNF.
- Store in a clinical refrigerator (+2°C to +8°C) within original packaging.
- Have access to a telephone.
- Stock control & storage of vaccines in accordance with national and local policies / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1in 1000 injection (as a minimum). (Please refer to PGD for adrenaline as applicable)

References

- NICE Good Practice Guidance 02 : Patient Group Directions Aug 2013
- Public Health England*:* Immunisation Against Infectious Disease - The "Green Book" Chapter 33: Typhoid (August 2015). Accessed at https://www.gov.uk/government/publications/typhoid-the-green-book-chapter-33 on 19th February, 2017.
- British National Formulary (BNF), Accessed at http://www.bnf.org/bnf/index.htm on 19th February 2017
- Nursing and Midwifery Council (NMC), 2007: Standards for Medicines Management.
- Nursing and Midwifery Council (NMC), 2007: Record Keeping Advice Sheet.
- NMC, 2008: Code of Professional Conduct: standards of conduct, performance & ethics for nurses and midwives.
- Resuscitation Council (UK), October 2015: Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. www.resus.org.uk/siteindx.htm
- Sanofi Pasteur; Typhim Vi ® vaccine – SPC, 03/02/17 (accessed from Electronic Medicines Compendium on 19.02.17).
- GlaxoSmithKline Ltd; Typherix ® vaccine – SPC, 16/06/15 (accessed from Electronic Medicines Compendium on 19.02.17).
- PaxVax Ltd; Vivotif ® capsules – SPC, 09/01/17 (accessed from Electronic Medicines Compendium on 19.02.17).

4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically <u>authorised by their clinical lead/supervisor/manager</u> may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Nurses	Chiropodists/Podiatrists
Health Visitors	Physiotherapists	Midwives
Dieticians	Optometrists	Registered Orthoptists
Prosthetists and Orthotists	Radiographers	Occupational Therapists
Speech and Language Therapists	Dental Hygienists	Dental Therapists
State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.		

Qualifications required (professional registration applies to specific professions**)**

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council

Additional requirements (applies to all staff)

- Maintain knowledge of vaccinations; either through a recognised course or through in-house training supported by attendance at vaccination study day(s).
- Meet the HPA National minimum standards in immunisation training 2005 either through training or professional competence ensuring that annual training is offered to all staff
- Have up to date resuscitation skills and anaphylaxis training (and competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current authorised Adrenaline PGD.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and *Immunisation Against Infectious Disease* (Green Book online version).
- Any additional training requirements as deemed necessary by your organisation or authorising body.

Continued training requirements (applies to all staff)

- Annual attendance at an update on resuscitation skills and the management of anaphylaxis within the community/primary care **(mandatory).**
- Maintenance of own level of updating and competence with evidence of continued professional development.
- Annual updates in immunisation **(recommended).**
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

Management & Monitoring of Patient Group Direction NECSAT 2017/004

The Administration of

TYPHOID VACCINES
(Typhim Vi, Typherix® and Vivotif®)

Individual Healthcare Professional Authorisation

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional:-_____

I have read and understood the Patient Group Direction.

TYPHOID VACCINES

I agree to administer Typhoid Vaccines only in accordance with this PGD (NECSAT 2017/004)

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

Authorisation to use this PGD by: -

I agree that the above named healthcare professional is authorised to administer medicines in accordance with this PGD by:

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

PGD Valid from: 1st March 2017	Review Date: - Dec. 2018	**Expiry Date: - 31st March 2019**

Management & Monitoring of Patient Group Direction NECSAT 2017/004

The Administration of

TYPHOID VACCINES

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

Typhoid Vaccines under the Patient Group Direction (NECSAT 2017/004)

PGD Valid from date: 1st March 2017 **PGD Expiry Date:** 31st March 2019

Healthcare Professional			**Authorised by:**		
Name	**Signature**	**Date**	**Name**	**Signature**	**Date**

PGD Valid from: 1st March 2017	Review Date: - Dec. 2018	**Expiry Date: - 31st March 2019**