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PATIENT GROUP DIRECTION (PGD)

Administration of typhoid Vi polysaccharide vaccine to overseas travellers at risk of exposure to *Salmonella enterica serovar typhi* (*S. typhi*) in accordance with recommendations from the National Travel Health Network and Centre (NaTHNaC).

This PGD is for the administration of typhoid Vi polysaccharide vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	Typhoid Vi vaccine PGD
Version no:	V01.00
Valid from:	01 March 2018
Review date:	01 September 2019
Expiry date:	29 February 2020

Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended.

Operation of this PGD is the responsibility of commissioners and service providers.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

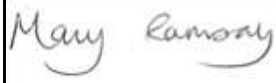
[1] This includes any relevant amendments to legislation (eg 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE typhoid Vi vaccine PGD	30 January 2018

1. PGD template development

This PGD template has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		01/02/2018
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		01/02/2018
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		01/02/2018

This PGD template has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Dipti Patel	NaTHNaC Director, Public Health England
Lisa Rees	Medicines Management Pharmacist, Bristol Clinical Commissioning Group
Tushar Shah	Pharmacy Advisor, NHS England London Region
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East
Sharon Webb	Programme Manager - IDPS , NHS Screening Programmes, Public Health England (Midwife)

2. 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. The authorising body accepts governance responsibility for the appropriate use of the PGD.

INSERT AUTHORISING BODY NAME authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
eg All NHS England commissioned immunisation services or NHS Trust providing immunisation services.
Limitations to authorisation
eg Any local limitations the authorising organisation feels they need to apply in-line with the way services are commissioned locally. This organisation does not authorise the use of this PGD by ….

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Complete eg NHS England Governance Lead, Medical Director			

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to…….

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • 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 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 • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Continued training requirements	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). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals against *S. typhi* infection in accordance with national recommendations in Chapter 33 of Immunisation Against Infectious Disease: "The Green Book" and NaTHNaC recommendations for typhoid vaccination for travel.
Criteria for inclusion	Adults and children over 2 years old who: • intend to travel, where typhoid vaccination is currently recommended for travel by NaTHNaC (see the Travel Health Pro website for country-specific advice on typhoid vaccination) Children aged 12 months up to 2 years (off-label use) who: • intend to travel, where typhoid vaccination is currently recommended for travel by NaTHNaC and if the risk of typhoid fever is considered high (see the Travel Health Pro website for country-specific advice on typhoid vaccination)
Criteria for exclusion[2]	Individuals for whom no valid consent has been received. Individuals who: • are under 12 months of age • have had a confirmed anaphylactic reaction to a previous dose of typhoid Vi polysaccharide vaccine or to any components of the vaccine (including trace components from the manufacturing process which may include formaldehyde, see SPC)* • are at increased risk of *S. typhi* infection because of their occupation (eg laboratory personnel who may handle *S. typhi* in the course of their work) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) *Note: Severe reactions to a previous dose of non-Vi typhoid vaccines do not contraindicate the subsequent use of a Vi-containing vaccine.
Cautions including any relevant action to be taken	Individuals who are immunosuppressed or have HIV infection may not make a full antibody response; consider whether postponing vaccination until the end of the disease or treatment is appropriate. Otherwise, vaccination is recommended even if the antibody response may be limited and the importance of scrupulous attention to personal, food and water hygiene must be emphasised. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
Action to be taken if the patient is excluded Continued over page	Individuals under one year of age are not recommended typhoid vaccine. Where vaccine is not recommended (and even when it is), the importance of stringent personal, food and water hygiene measures should be reinforced.

[2] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Action to be taken if the patient is excluded (continued)	Individuals who have had a confirmed anaphylactic reaction to a previous dose of typhoid Vi polysaccharide 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 *S. typhi* infection should be referred to their employer's occupational health provider for vaccination. 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. In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the patient or carer 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. 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. In a GP practice setting, inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength & formulation of drug	Typhoid Vi polysaccharide vaccine, 0.5ml dose containing 25 micrograms Vi polysaccharide of *S. typhi* (Ty2 strain) eg: • TYPHIM Vi® vaccine, solution for injection in a pre-filled syringe Note: This PGD does not cover the supply or administration of the live oral (Ty21a) typhoid vaccine, Vivotif®.[3]
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	TYPHIM Vi® vaccine may be administered off-label to children between the age of 12 months and two years if the risk of typhoid fever is considered to be high, in accordance with the recommendations in Chapter 33 of "The Green Book" and NaTHNaC. 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.
Route / method of administration Continued over page	Administer by intramuscular injection into the deltoid region of the upper arm. 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 by deep subcutaneous injection to reduce the risk of bleeding (see "The Green Book" Chapter 4). Typhoid Vi polysaccharide vaccine is a clear colourless solution. 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. Shake well immediately before administration. The vaccine's SPC provides further guidance on administration and

[3] PHE do not currently plan to produce a PGD for live oral (Ty21a) typhoid vaccine (Vivotif®) because, as a 3 dose oral course, an appropriately labelled supply would be required. Since the availability of such supplies cannot be assured when writing a national PGD template, oral vaccines may be better suited to provision by normal prescription and dispensing services.

Route / method of administration (continued)	is available from the electronic Medicines Compendium website: www.medicines.org.uk
Dose and frequency of administration	A single 0.5ml dose. Vaccination should occur at least 2 weeks prior to potential exposure to infection with *S. typhi*. Based on individual risk assessment, vaccination may be considered up until departure but protection may be limited. Revaccination: Individuals who plan to travel to an area where typhoid vaccination is currently recommended for travel by NaTHNaC, and who have not received typhoid vaccine in the preceding 3 years should be re-vaccinated against *S. typhi*. Individuals who remain at risk of exposure to *S. typhi* should be revaccinated every three years (see Special Considerations section). Note: Typhoid Vi polysaccharide vaccine may be used for revaccination when individuals have received non-Vi typhoid vaccine for the preceding dose.
Duration of treatment	Single dose. Revaccination may be indicated for individuals who remain at risk of typhoid fever (see Dose and frequency of administration).
Quantity to be supplied / administered	Single 0.5ml dose.
Supplies	Typhoid vaccine is not centrally supplied and should be obtained directly from manufacturers/wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3).
Storage	Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. 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.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing 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).

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Drug interactions	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
Identification & management of adverse reactions	Local reactions following vaccination are very common ie pain, swelling, erythema and induration at the injection site. Adverse reactions to typhoid Vi polysaccharide vaccines are usually mild and transient, disappearing a few days after immunisation. Other reported reactions to typhoid Vi polysaccharide vaccination include general symptoms such as fever, general aches, malaise, headache, nausea and itching. 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
Reporting procedure of adverse reactions	Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme at: http://yellowcard.mhra.gov.uk Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
Patient advice / follow up treatment	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. The individual/parent/carer should be advised that Typhoid Vi polysaccharide vaccine offers protection against typhoid fever caused by *S. typhi*, it does not prevent paratyphoid fever or infection with any other serotypes of *S. enterica*. The individual/parent/carer should be advised that protection by vaccination may be less if a large number of infective organisms are ingested. Because of the limited protection offered by the vaccine, the importance of scrupulous attention to personal, food and water hygiene must still be emphasised for those travelling to endemic areas. When applicable, advise individual/parent/carer when the subsequent dose is due. When administration is postponed advise the individual/parent/carer when to return for vaccination.

Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. Protective antibody titres to Vi antigen fall over time. Re-vaccination is necessary when continuing protection is required. Additional doses of Vi vaccine do not boost serum antibody levels; re-vaccination returns antibody levels to those achieved after the primary immunisation. Non-conjugated polysaccharide vaccines are poorly immunogenic in infants and young children. There is little definitive data on the efficacy of Vi vaccine in children aged less than 18 months. There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated vaccines. Since typhoid polysaccharide vaccine is an inactivated (subunit) vaccine, the risks to the foetus are negligible and it should be given where there is a definite risk of infection. Local Health Protection Team (HPT) should be informed immediately whenever a patient is suspected of having typhoid fever. Typhoid vaccine is not recommended for close contacts of either cases or carriers, or during an outbreak of typhoid fever in the UK. Both cases and carriers of *S. typhi* should be advised to be scrupulous in their hygiene practices. Carriers should be referred for specialist clinical management.
Records	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • 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 immunisation • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled immunisers 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 Systems team (Child Health Records Department) 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.

6. Key references

Key references	**Product** • Immunisation Against Infectious Disease: The Green Book Chapter 4, last updated June 2012 and Chapter 33, last updated 28 August 2015. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for TYPHIM Vi®, GlaxoSmithKline UK. Last updated 3 February 2017. http://www.medicines.org.uk/emc/medicine/6186 • Factsheet: Typhoid and paratyphoid. NaTHNaC. Last Updated 10 February 2016. https://travelhealthpro.org.uk/factsheet/49/typhoid-and-paratyphoid https://travelhealthpro.org.uk/countries **General** • British National Formulary (BNF) and British National Formulary for Children (BNF-C). Accessed 22 November 2017. https://bnf.nice.org.uk/drug/typhoid-vaccine.html https://bnfc.nice.org.uk/drug/typhoid-vaccine.html • 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 • Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336 • National Minimum Standards for Immunisation Training https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards • 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. January 2014. 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 • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

7. Practitioner authorisation sheet

Typhoid Vi vaccine PGD v01.00 Valid from: 01/03/2018 Expiry: 29/02/2020

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

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 of conduct.

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.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **INSERT NAME OF ORGANISATION** for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.