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Grampian Highland Orkney Shetland Tayside Eileanan Siar Western Isles

Patient Group Direction For The Administration Of Typhoid Vaccine Injection By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian

Signature:		**Signature:**

NoS Identifier: NoS/PGD/Typhoid/ MGPG1189	**Review Date:** November 2023 **Expiry Date:** November 2024	**Date Approved:** November 2021

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 8

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NHSG/PGD/typhoid/MGPG933 Version 7.1	
Date of change	**Summary of Changes**	**Section heading**
August 2021	NHS Highland, Tayside and Western Isles added to existing NoS PGD.	

NoS Identifier: NoS/PGD/Typhoid/MGPG1189
Keyword(s): PGD Patient Group Direction Typhoid, TYPHIM, vaccine Nurse Pharmacist

Policy Statement: It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	August 2021
	Completed:	October 2021
	Approved:	November 2021 (published – December 2021)
	Amended and reauthorised:	

Organisational Authorisations

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

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Diana Webster **Health Board:** NHSG **Title:** Public Health Consultant **Contact email:** diana.webster@nhs.scot **Signature:** DWebster **Date signed:** 20/12/2021
Senior representative of the professional group who will provide care under the direction	**Name:** John Fowlie **Health Board:** NHSG **Title:** Community Pharmacist **Contact email:** john.fowlie2@nhs.scot **Signature:** ..... **Date signed:** 14/12/2021
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature:** F Adamson **Date signed:** 07/12/20221
Pharmacist	**Name:** Liam Callaghan **Health Board:** NHSWI **Title :** Chief Pharmacist **Contact email:** liam.callaghan@nhs.scot **Signature:** L Callaghan **Date signed:** 13/12/2021

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		24/11/2021

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		20/12/2021

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	**Title:**
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Liam Callaghan	**Pharmacist:** Chief Pharmacist NHSWI
Dr Diana Webster	**Medical Practitioner:** Public Health Consultant NHSG
John Fowlie	**Senior Representative:** Community Pharmacist NHSG
Sarah Buchan	Pharmaceutical Care Services Manager NHSG
Jackie Agnew	Head of Community Pharmacy NHSH
Andrew Radley	Consultant in Public Health Pharmacy NHST
Russell Mackay	Systems Lead Pharmacist NHSO
Mary McFarlane	Principal Pharmacist NHSS

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Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer typhoid vaccine to individuals aged 2 years and over. **Note:** The **oral** typhoid vaccine Vivotif® is **not** covered by this PGD. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book, TRAVAX, NaTHNaC and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	• 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. • Laboratory personnel who may handle *Salmonella. typhi* in the course of their work. • Essential groups as designated by Occupational Health or Consultant in Public Health Medicine (CPHM). Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals: • Under 2 years of age. • With current acute systemic or febrile illness. • Who have had a known anaphylactic reaction to any component of the typhoid vaccines or a life-threatening reaction after previous administration of the vaccine, or a vaccine containing the same substances and any of the excipients. • Who have a hypersensitivity to formaldehyde. • Where there is no valid consent.

Precautions and special warnings	• Prior to administration of typhoid vaccine the recipient or their guardian must be asked about the recipient's personal history, current health status and any adverse event after previous immunisations. If the individual has had a significant local or general allergic reaction to a previous administration of typhoid vaccine, refer to doctor or travel health specialist. • Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered. • The immunogenicity of typhoid vaccine may be reduced by immunosuppressive treatment or immunodeficiency. In such cases it is recommended to postpone vaccination until the end of the disease or treatment. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the antibody response might be limited. Refer to an appropriate medic. • Individuals with a Bleeding Disorder - An individual risk assessment should be undertaken prior to vaccination. As with any intramuscular (IM) vaccination, the injection should be given with caution to individuals with thrombocytopenia or any coagulation disorder, as bleeding may occur following IM administration. Therefore, individuals with known bleeding disorders or taking anticoagulant therapy should receive the vaccine by deep subcutaneous injection route to reduce the risk of bleeding. Individuals should be informed of the risk of developing haematoma and what to do if this occurs.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner If clarification is required about an individual meeting the exclusion criteria advice should be sought from the individual Board Health Protection team or travel health specialist. The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.

Action if treatment is declined	Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached. Inform/refer to the relevant medical practitioner if individual/person with parental responsibility declines treatment. Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.

Description of vaccine available under the PGD

Name form and strength of vaccine	TYPHIM Vi® (0.5mL single dose pre-filled syringe). Typhoid Polysaccharide vaccine is clear colourless solution available in a pre-filled syringe. Each dose (0.5mL) contains 25 micrograms of purified Vi polysaccharide of *Salmonella typhi* (Ty2 strain) preserved with phenol.
Legal status	Typhoid vaccine (TYPHIM Vi®) is Prescription-only Medicine (POM). Pregnancy and lactation - No data are available on the safety of Vi polysaccharide vaccines in pregnancy or during lactation. There is no evidence of risk from vaccinating pregnant women, or those who are breastfeeding. If the risk of typhoid is high, vaccination should be considered. This is a DH Green Book recommendation which may be out with the relevant SmPC. The individual or the person with parental responsibility should be informed prior to the administration that the use is off-label.
Dosage/Maximum total dose	For adults and children over two years of age: A single dose (0.5mL) should be given.
Frequency of dose/Duration of treatment	**Primary course:** Single Injection. Vaccination should occur at least 2 weeks prior to potential exposure to infection with *Salmonella typhi*. **Booster:** Individuals who remain at risk of typhoid fever should be re-vaccinated using a single dose of typhoid polysaccharide vaccine every 3 years.

Maximum or minimum treatment period	N/A
Route/Method of administration	Administration of the vaccine should be by intramuscular (IM) and the preferred site is the upper arm or anterolateral thigh. Individuals with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding. This vaccine **should not be given** by the intravenous or intradermal routes under any circumstances. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to TYPHIM Vi®. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records. The vaccine should be well shaken immediately before use and must be visually inspected for foreign particles or variation of physical aspect before use.
Quantity to be administered	0.5mL.
Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Store in original packaging in order to protect from light. Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed.
Follow-up (if applicable)	Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice. Where proof of vaccination is required, a certificate, stamped vaccination booklet or equivalent must be supplied.

Advice (Verbal)	Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions. If serious adverse or persistent effects occur, the individual/person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24. When administration is postponed advise the individual/person with parental responsibility when to return for vaccination.
Advice (Written)	The PIL contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Further information on travel health is available at https://www.fitfortravel.nhs.uk/home
Identifying and managing possible adverse reactions	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. The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site. Other commonly reported symptoms include; Fatigue Headache Malaise Diarrhoea Fever Arthralgia Nausea Abdominal Pain Itching Myalgia Vomiting Individual may also experience stiffness in the arm for a few days following injection. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

	This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions. **BNF/BNFC**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the vaccine is to be administered: • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	Registered Nurses as recognised by the Nursing and Midwifery Council (NMC), and Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/person with parental responsibilities capacity to understand the nature and purpose of vaccination in order to give or refuse consent

	• Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken PGD training as required/set out by each individual Health Board • Have attended basic life support training either face to face or online and updated in-line with individual Board requirements • Have undertaken immunisation training where available • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements • Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct • Have knowledge and familiarity of the following; o Current edition of the Green Book o SmPC for the vaccine to be administered in accordance with this PGD o Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board o Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.

Documentation

Authorisation of administration	Nurses working within NHS Shetland can be authorised to administer the drug specified in this PGD by their Nurse Manager/Consultant/Practice GPs.

	Pharmacists working within NHS Grampian, Highland, Orkney, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of administration	An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of vaccine administration • Individuals name and CHI • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/site of the vaccination administered • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate. • Individual's GP records if appropriate • Individual service specific systems.
Audit	All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.

References	Electronic Medicines Compendium http://www.medicines.org.uk TYPHIM Vi® - Date of revision of text 15/12/20, accessed 10/08/21. British National Formulary for Children and the British National Formulary accessed 10/08/21. BNF British National Formulary - NICE BNF for Children British National Formulary - NICE Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33. Travax http://www.travax.nhs.uk/ accessed 10/08/21. National Travel Health Network and Centre www.NaTHNaC.org accessed 12/08/21.

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

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I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group Direction For The Administration Of Typhoid Vaccine Injection By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**