NHS Grampian

Patient Group Direction For The Administration Of Typhoid Vaccine Injection By Occupational Health Nurses Working Within NHS Grampian

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 has authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within NHSG. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 8.1 (Amended September 2022)

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NHSG/PGD/typhoid/MGPG1189 Version 8	
Date of change	**Summary of Changes**	**Section heading**
August 2022	Wording changed in title for use only in OHS.	Throughout
August 2022	Travel indications removed from PGD.	Throughout
August 2022	Age for inclusion in PGD raised to 16 years from 2 years.	Throughout
August 2022	Pregnancy and breastfeeding added as exclusions.	Exclusion criteria

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

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 re-authorised:	September 2022

Organisational Authorisations

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

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Katherine Targett **Title:** Consultant in Occupational Health Medicine **Contact email:** katherine.targett@nhs.scot **Signature:** ..... **Date signed:** 02/11/2022
Senior representative of the professional group who will provide care under the direction	**Name:** Rhiannon Sharp **Title:** Occupational Health Nurse **Contact email:** rhiannon.sharp@nhs.scot **Signature:** ..... **Date signed:** 02/11/2022
Lead author	**Name:** Frances Adamson **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature:** ..... **Date signed:** 02/11/2022
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Approved for use within NHSG by;

Medicines Guidelines and Policies Group Chair	Signature	Date Signed
Lesley Coyle		04/11/2022

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
Alison Smith	**Pharmacist:** Medicines Management Pharmacist
Dr Katherine Targett	**Medical Practitioner:** Consultant in Occupational Health Medicine
Rhiannon Sharp	**Senior Representative:** Occupation Health Advisor
Sarah Buchan	Pharmaceutical Care Services Manager

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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 16 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), The Green Book and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Laboratory personnel aged 16 years and over who may handle *Salmonella. typhi* in the course of their work. 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 NHSG consent policy.
Exclusion criteria	Individuals: • Under 16 years of age. • With current acute systemic or febrile illness. • Who are pregnant or breastfeeding. • Who 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 or casein, see SmPC). Severe reactions to a previous dose of non-Vi typhoid vaccine do not contraindicate the subsequent use of a Vi-containing vaccine. • Who have a hypersensitivity to the active substance, to any of the excipients or to any residual substances that may be present as traces such as formaldehyde or casein. Individuals for whom no valid consent has been received.
Precautions and special warnings	Prior to administration of typhoid vaccine the recipient must be asked about their personal medical 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.

	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. 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 Pre-exposure Vaccine Prophylaxis.	Medical advice must be sought – refer to relevant medical practitioner. 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 Pre-exposure Vaccine Prophylaxis 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 declines pre-exposure vaccine prophylaxis. 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 25micrograms of purified Vi polysaccharide of *Salmonella typhi* (Ty2 strain) preserved with phenol.
Legal status	Typhoid vaccine (TYPHIM Vi®) is Prescription-only Medicine (POM).

Dosage/Maximum total dose	0.5mL single dose
Frequency of dose/Duration of treatment	Single Injection. A single dose of Vi vaccine should be administered at three-year intervals in adults and children over two years of age who remain at risk from typhoid fever. Individuals who have received other non-Vi typhoid vaccines may receive reinforcing doses of Vi vaccine at three-year intervals.
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. Do not freeze. Store in original packaging in order to protect from light.

	NHSG guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, NHSG 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.
Advice (Verbal)	Advise individual what to expect and what to do for minor and major reactions. If serious adverse or persistent effects occur, the individual 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.
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. It is important that procedures are in place to avoid injury from faints 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 Individuals 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** BNF 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. Document in accordance with locally agreed procedures in the individual's record. Report any suspected adverse 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	Nurses currently registered with the Nursing and Midwifery Council (NMC).

Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's 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 recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • 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 module training on TURAS • Have attended basic life support training either face to face or online and updated in-line with NHSG 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 NHSG requirements • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the vaccine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD. • Have knowledge and familiarity of the following; ○ Current edition of the Green Book ○ SmPC for the vaccine to be administered in accordance with this PGD ○ Relevant policy relating to vaccine storage and immunisation procedures for use within NHSG ○ 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	Registered nurses working within NHS Grampian OHS can be authorised to administer the vaccine specified in this PGD by their line manager/occupational health doctor. 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.
Record of administration	An electronic or paper record must be completed to allow audit of practice. An electronic/Hospital Electronic Prescribing and Medicines Administration (HEPMA) record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with NHSG electronic/HEPMA recording processes. If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD, it 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. • HEPMA • 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 07/09/2022. British National Formulary accessed 07/09/2022. 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.

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

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 they are 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 they understand and are 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 their individual code of professional practice and conduct.
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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

Patient Group Direction For The Administration Of Typhoid Vaccine Injection By Occupational Health Nurses Working Within NHS Grampian					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**