

PATIENT GROUP DIRECTION


For Administration of Typhoid Polysaccharide Vaccine for Injection to Adults and Children over 2 years of age

Issue Date: July 2010

PGD expiry date: July 2012

Please check with the clinical lead, medicines management team or PCT website www.cambridgeshire.nhs.uk for the most recent version of the PGD before proceeding.

Names and signatures of the multidisciplinary group which drew up this PGD

NAME	DESIGNATION/TITLE	SIGNATURE	DATE
Dr Lincoln Sargeant	Consultant in Communicable Disease Control	Signed by e-mail	14/7/10
Val Shaw	Pharmacist	 ty	8/7/10
Jan Gower	Practice Clinical Governance Lead Nurse	Signed by e-mail	19/7/10

Approved by	NHS Cambridgeshire Commissioning Medication Clinical Safety Group	28/7/10
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Signatures for Ratification

NAME	DESIGNATION/TITLE	SIGNATURE	DATE
1. Sue Ashwell	Chief Pharmacist	Signed by e-mail	20/7/10
2. Christine MacLeod	Medical Director	Signed by e-mail	20/7/10

Authorisation of Employer (if not employed by NHS Cambridgeshire)

NAME	DESIGNATION/TITLE	SIGNATURE	DATE

Each registered practitioner authorised to supply and/or administer medication under this PGD must have read, understood and signed this version of the PGD and completed the agreement to practice form before attempting to work according to it

Document Control Sheet

Rationale	A Patient Group Direction (PGD) is a specific, written instruction for the supply or administration of a named medicine in an identified clinical situation to patients who may not be individually identified before presentation for treatment.
Documents replaced or superseded by this PGD.	The following Patient Group Directions should no longer be used. Any signed-up copies should be archived: Typhoid vaccine for Injection to Adults and Children over 12 months of age Cambridgeshire PCT Expiry Date: May 2010 NHS Cambridgeshire Expiry Date: May 2012
Development & Consultation:	Updated by the multidisciplinary team from the previous PGD as listed above.
Dissemination	All General Practice Surgeries via Practice Managers for the attention of Practice Nurses. NHS Cambridgeshire website: www.cambridgeshire.nhs.uk
Accessibility	NHS Cambridgeshire website www.cambridgeshire.nhs.uk
Implementation	Practice and other Nurses responsible for vaccinating people in the included groups Each registered practitioner authorised to supply and/or administer medication under this PGD must have read, understood and signed it and completed the Agreement to Practice form before attempting to work according to it. The current Immunisation Against Infectious Diseases, 'The Green Book', must be checked before each vaccination clinic to ensure the information in this PGD is correct, this is available online at: http://www.dh.gov.uk/greenbook , any discrepancies must be reported to the Practice Nurse Clinical Governance Lead Nurse.
Training	See PGD
Audit	See PGD
Review	Clinical lead responsible for ensuring review: Practice Nurse Clinical Governance Lead Nurse. Review should be initiated 3 months before the expiry date unless a review is required in response to a change to the medicine(s) covered by this PGD
Equality and Diversity	Clinical lead responsible for ensuring review: Practice Nurse Clinical Governance Lead Nurse. Review should be initiated 3 months before the expiry date unless a review is required in response to a change to the medicine(s) covered by this PGD

Standards for Better Health

(PGDs will continue to be measured against DH Standards for Better Health until the alternative set of standards based on the Care Quality Commission registration requirements has been evaluated)

Domain	How?
Safety	PGD documentation provides consistent approach to patient care This document sets out the information specified in law as that required for a Patient Group Direction.
Clinical & Cost Effectiveness	PGDs are evidence based. They allow the patient to be treated by the most appropriate health professional at the first point of contact.
Governance	PGD ensures standardisation of care. PGDs are a legal requirement for healthcare professionals (who are not independent prescribers) to be able to administer or supply medicines without a prescription. Practitioners working under the PGD must sign up to it and keep the specified records, thus providing an audit trail and accountability.
Patient Focus	Healthcare professionals respond to patients' needs in an appropriate and timely manner. It is specified that all aspects of the patients treatment, including any medicines supplied or administered are discussed with the parent/ guardian Every patient is treated as an individual
Accessible and Responsive Care	Healthcare professionals respond to patients' needs in an appropriate and timely manner. The documentation allows specified healthcare professionals to supply or administer medicines without a prescription.
Care Environment & Amenities	None
Public Health	Typhoid vaccination is a public health mechanism for prevention of spread of this communicable disease worldwide Health promotion is an integral part of the consultation

3. Medicine to be administered under this Patient Group Direction	
3.1 Name, strength and form of medicine(s)	Vi capsular polysaccharide typhoid vaccine (Typherix®, Typhim Vi®) 25 micrograms in 0.5ml
3.2 Legal Status	POM
3.3 ▼ Black triangle	No
3.4 PGD covering use outside terms of Summary of Product Characteristics (SPC)?	No
3.5 Route /Method of administration	Intramuscular injection Subcutaneous route should be used for patients with bleeding disorders
3.6 Dose	0.5ml
3.7 Frequency	Single dose at least 2 weeks prior to risk of exposure. Subjects who remain at risk of typhoid fever (e.g. laboratory workers) should be revaccinated using a single dose of vaccine with an interval of not more than 3 years to ensure continuous protection against S. typhi.
3.8 Cautions	No additional cautions
3.9 Interactions with other medicines See also any interactions listed as exclusions	The immunogenicity of the vaccine may be reduced by immunosuppressive treatment or immunodeficiency See current Green Book, SPC or BNF Appendix 1
3.10 Potential adverse reactions/ side effects	<ul style="list-style-type: none"> Local reactions, including pain, swelling or erythema, may appear 48 – 72 hours after administration. Patients may experience temporary headache / feverishness.
3.11 Instructions on identifying and managing Adverse Drug Reactions	<ul style="list-style-type: none"> Advise patient/ parent/ guardian on management of the adverse effect Report any suspected ADR to a medical practitioner as soon as possible if clinically relevant. Use the Yellow Card System to report adverse drug reactions directly to the Committee on Safety of Medicines (MHRA). Guidance on the use of the Yellow Card System and Yellow Cards are available in the current BNF
3.12 Advice to patient/ parent/ guardian	<ul style="list-style-type: none"> Vaccination is not a substitute for scrupulous personal hygiene. Inform of possible side effects and their management. Give advice on body temperature control Individuals must be given enough information to enable them to make a decision before they consent to treatment under this PGD. Provide the manufacturer's Patient Information Leaflet if possible and national information leaflets. Explain treatment and any further instructions to aid compliance/ concordance Advise patient/ parent/ guardian to seek medical advice in case of severe or unexpected adverse effects
3.13 Follow up	Repeat dose every 3 years on continued exposure
3.14 Storage and Handling	+2°C to +8°C in a refrigerator Do not freeze. Discard if frozen. Shake before use
3.15 Advice on concurrent medication	Separate injection sites must be used in case of concomitant vaccine administration.

	<p>administered</p> <ul style="list-style-type: none"> • Full name, signature and registration of practitioner administering dose, or record in patient's notes on clinical system • Batch number • Expiry date
5.3 Audit	<ul style="list-style-type: none"> • Annual audit must be carried out by the clinical lead • Records of patients who have received treatment under the PGD must be accessible for audit purposes • Regulations require that there is a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient-by-patient basis. <p>Audit may include evidence of authorised practitioners signatures, appropriate supply, standards of documentation, follow up arrangements, advice and information given to parent/ guardians, reporting of adverse effects and incidents.</p>

6. References

- <http://emc.medicines.org.uk/> Summary of Product Characteristics, Typherix®, GlaxoSmithKline UK, last updated 3/11/09, accessed 22 May 2010.
- <http://emc.medicines.org.uk/> Summary of Product Characteristics, Typhim Vi®, Sanofi Pasteur MSD, last updated 08/2009 , accessed 22 May 2010.
- Department of Health 2006: Immunisation against Infectious Disease (accessed 22 May 2010) available at http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254
- Department of Health: Vaccine Update Issue 146; Green Book Updates, Chapter 33 Typhoid updated 9 Feb 2009
- Health Protection Agency 2005: National Minimum Standards for Immunisation Training
- Martin J Ed. British National Formulary No 59 March 2010. BMA and RPSGB Pharmaceutical Press (accessed 21 May 2010)
- HSC 2000/026, 9th August 2000 Patient Group Directions (England)

AGREEMENT BY HEALTH PROFESSIONAL TO ACT UNDER THE PATIENT GROUP DIRECTION

I have read and fully understand the following documents:

The Patient Group Direction: For Administration of Typhoid Vaccine to Adults and Children over 24 months of age

Dated: Expiry date:

BNF and SPC monographs for all drugs included in this PGD.
The NHS Cambridgeshire Patient Group Direction Policy

I agree to act within the terms of the Patient Group Direction and administer and/or supply medicines in accordance with the documents listed above.

I understand that my employer e.g. GP practice or NHS Cambridgeshire is vicariously liable for acts and omissions by me during my employment with them.

I understand that failure to comply with the terms and conditions of the PGD, including the expiry date and limitations on practitioners, patients, drugs and indications may render me liable to disciplinary action by my employer e.g. GP practice or PCT under their performance and conduct arrangements.

NAME: *(block capitals)* (Health Professional)

SIGNATURE: (Health Professional)

POSITION:

EMPLOYER:

SITE/ PRACTICE:

DATE SIGNED:

The original must be filed in the health professional's personal file and a copy held by their manager or employer for the purposes of ensuring practice occurs only in accordance with the PGD and is only undertaken by approved practitioners.