

PATIENT GROUP DIRECTION


For Administration of Hepatitis A Vaccine for Adults and Children over 1 year

Issue Date: May 2010

PGD expiry date: May 2012

Please check with the clinical lead, medicines management team or NHS Cambridgeshire 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 Public Health	Signed by e-mail	23/5/10
Val Shaw	Pharmacist	 Hep A	22/5/10
Jan Gower	Clinical Governance Nurse	Signed by e-mail	23/5/10

Approved by	The NHSC Commissioning Medication Clinical Safety Group	26/5/10
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Signatures for Ratification

NAME	DESIGNATION/TITLE	SIGNATURE	DATE
1.Sue Ashwell	Chief Pharmacist	Signed by e-mail	24/5/10
2.Dr Christine MacLeod	Medical Director	Signed by e-mail	25/5/10

Authorisation of Employer (if not employed by Cambridgeshire PCT)

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Documents replaced or superseded by this PGD.	<p>The following Patient Group Directions should no longer be used. Any signed-up copies should be archived:</p> <p>Hepatitis A Vaccine for Adults –</p> <ul style="list-style-type: none"> • East Cambs and Fenland PCT Expiry Date: December 2007 • Huntingdonshire PCT Expiry Date: June 2008 <p>Hepatitis A Vaccine for Children –</p> <ul style="list-style-type: none"> • East Cambs and Fenland PCT Expiry Date: December 2007 • Huntingdonshire PCT Expiry Date: June 2008 <p>Hepatitis A Vaccine for Adults and Children –</p> <ul style="list-style-type: none"> • Cambridge City and South Cambs PCT Expiry Date: June 2008 • Cambridgeshire PCT Expiry Date: March 2010
Development & Consultation:	Updated by the multidisciplinary team listed above.
Dissemination	All General Practice Surgeries via Practice Managers for the attention of Practice Nurses. NHS Cambridgeshire website: www.cambridgeshire.nhs.uk and www.cambridgeshire.nhs.uk
Accessibility	NHS Cambridgeshire website www.cambridgeshire.nhs.uk and www.cambridgeshire.nhs.uk
Implementation	Practice and other Nurses responsible for delivering the national childhood immunisation schedule. 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 referred to the Practice Clinical Governance Lead Nurse.
Training	See PGD
Audit	See PGD
Review	Clinical lead responsible for ensuring review: Practice 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	The NHSC Commissioning Medication Clinical Safety Group has carried out a Rapid Equality & Diversity Impact Assessment and concluded the document is compliant with the PCT Equality and Diversity Policy.

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 a 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	
Public Health	Immunisation against Hepatitis A is part of the government's programme for the prevention of the spread of infectious diseases. Health promotion is an integral part of the consultation

1. Staff Authorised to administer the medicine under the Patient Group Direction (PGD).	
1.1 Professional qualification	Registered Nurse (current registration with NMC)
1.2 Specialist qualifications, training, experience and competence that must be achieved relevant to the clinical conditions and medicines used.	<p>Training and competence in all aspects of using PGDs and immunisations, including contraindications.</p> <p>In addition all authorised staff must demonstrate an appropriate level of understanding and knowledge with regards to:</p> <ul style="list-style-type: none"> • Assessment of patient • The medication, therapeutic use, side-effects, interactions and storage and handling requirements • Have undertaken basic life support and anaphylaxis training and receive annual updates • Be familiar with the relevant NHSC and employer's medicines policies (see 1.4 below)
1.3 Continuing Professional Development Requirements (CPD)	<ul style="list-style-type: none"> • Be able to demonstrate annual Immunisation Training Updates have been undertaken. • All registered professionals are professionally accountable and must work within their competence. • A record of training and competence must be maintained in the individual's personal file. • The agreement to practice form for this PGD is kept in the individual's personal file and a copy retained by the clinical lead. • The practitioner must be aware of any changes to the recommendations for the medicine(s) listed and changes to national guidance. • It is the responsibility of the individual to maintain and improve their professional knowledge and skills in this area of practice. • Continued updating of relevant knowledge from current web-based version of Immunisation against Infectious Disease (Green Book), this is available online at: http://www.dh.gov.uk/greenbook
1.4 Documents to be read in conjunction with this PGD	<ul style="list-style-type: none"> • NHS Cambridgeshire Patient Group Direction Policy • NHS Cambridgeshire/ Employing Practice's Anaphylaxis Policy • NHS Cambridgeshire/ Employing Practice's Cold Chain Policy • Relevant Practice Policies • Practitioners must check the current Department of Health 2006: Immunisation against Infectious Disease (the "Green Book") latest update before each vaccination clinic to ensure the information in this PGD is correct at: http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254 • Emergency treatment of anaphylactic reactions – Guidelines for Healthcare Providers – Resuscitation Council (UK) available online at: http://www.resus.org.uk/pages/reaction.pdf with the following algorithm http://www.resus.org.uk/pages/anaalgo.pdf • Current SPC and BNF

2. Clinical condition or situation to which this Patient Group Direction applies	
2.1 Clinical condition/ situation	Adults and Children over 1 year requiring protection from Hepatitis A
2.2 Inclusion criteria	<ul style="list-style-type: none"> • Laboratory staff who work directly with the virus • Workers at risk of exposure to untreated sewage • Staff and residents of care homes for those with severe learning difficulties • People who work with primates. • Travellers to high-risk areas (see current edition of BNF, or for latest information the following websites: Travax (access using Username : DWELL93747 Password: 908-463) www.travax.scot.nhs.uk or www.nathnac.org for details) • Parenteral drug abusers • Individuals at risk because of their sexual behaviour • Patients with chronic liver disease • Patients with haemophilia receiving plasma-derived clotting factors. • Previously unvaccinated contacts of cases of hepatitis A, within 7 days of onset of disease/ jaundice in the primary case • Patients with chronic Hepatitis B or C infection
2.3 Exclusion criteria	<p>NB: Patients may be excluded by cautions or interactions - see Section 6.1.</p> <ul style="list-style-type: none"> • Children under 1 year old • Current severe febrile illness (see Green Book) • Confirmed anaphylactic reaction to a preceding hepatitis A vaccination • Known hypersensitivity to any component of the vaccine, including formaldehyde (Havrix®, Avaxim® and Vaqta® paediatric brands may contain trace amounts of neomycin) • Pregnancy and lactation • Epaxal® brand only – hypersensitivity to eggs or chicken protein
2.4 Actions to be taken regarding care of excluded patients	<ul style="list-style-type: none"> • Reschedule or refer to General Practitioner as clinically indicated • Discuss with patient and document the reasons for exclusion from treatment under the PGD • Specialist advice must be sought on the vaccines and circumstances under which they could be given. The risk to the individual of not being immunised must be taken into account
2.5 Consent	<ul style="list-style-type: none"> • The proposed treatment including the risks, benefits and side effects must be explained to the patient and verbal consent obtained and recorded in the notes.

2.6 Actions for patients who do not wish to receive care under this PGD	<ul style="list-style-type: none"> • Advise about protective effects of the vaccine and the risks of infection and disease complications. • Document advice given. • Document refusal in notes. • Seek medical advice if necessary
2.7 Reasons for referral or for seeking medical advice	<ul style="list-style-type: none"> • Previously unvaccinated contacts of cases of hepatitis A presenting after 7 days of onset of disease/ jaundice in the primary case should be referred for medical advice as vaccination may still be beneficial • Exclusions or patient preference as above • If there are any concerns or cautions/interactions relating to the medicine to be given, practitioners should seek medical advice or refer/transfer to the appropriate prescriber/ service if necessary
3. Medicine to be administered under this Patient Group Direction	
3.1 Name, strength and form of medicine(s)	<p>Inactivated Hepatitis A vaccine (e.g. Avaxim®, Havrix monodose®, Epaxal®)</p> <p>Inactivated Hepatitis A vaccine (Junior) (e.g. Havrix Junior Monodose®, Vaqta Paediatric®)</p>
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, deltoid region preferred. In exceptional circumstances the subcutaneous route may be used for patients at risk of haemorrhage.
3.6 Dose	<p>Adult dosage (age 16 and over):</p> <ul style="list-style-type: none"> • Avaxim®: 0.5ml • Epaxal®: 0.5ml • Havrix monodose®: 1ml <p>Children:</p> <ul style="list-style-type: none"> • Havrix junior monodose® 1-15 years 0.5ml • Vaqta Paediatric® 1-17 years 0.5ml • Epaxal®: over 1 year 0.5ml <p>Other brands – see individual SPC.</p>

<p>3.7 Frequency</p>	<p>Primary course: - single dose, followed after 6 – 12 months by a booster dose. However, studies have shown that successful boosting can occur even when the second dose is delayed for several years, so a course does not need to be restarted (check current SPC or BNF).</p> <p>A further booster dose is indicated after 20 years for those at ongoing risk.</p> <p>For travellers, vaccine should preferably be given at least two weeks before departure, but can be given up to the day of departure.</p> <p>If departing within 2 weeks, discuss the risks associated with reduced cover.</p>
<p>3.8 Cautions</p>	
<p>3.9 Interactions with other medicines See also any interactions listed as exclusions</p>	<p>See current Green Book: http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254</p> <p>SPC: http://emc.medicines.org/</p> <p>BNF Appendix 1: www.bnf.org For interactions with other medicines information about immunosuppressive treatment or immunodeficiency as the immunogenicity of the vaccine may be reduced</p>
<p>3.10 Potential adverse reactions/ side effects</p>	<p>Mild local reactions may occur Rarely, anaphylaxis</p>
<p>3.11 Instructions on identifying and managing Adverse Drug Reactions</p>	<ul style="list-style-type: none"> • Advise patient 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
<p>3.12 Advice to patient</p>	<ul style="list-style-type: none"> • Inform of possible side effects and their management. • 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 <p>Advise patient to seek medical advice in case of severe or unexpected adverse effects</p>
<p>3.13 Follow up</p>	
<p>3.14 Storage and</p>	<p>+2°C to +8°C in a refrigerator</p>

Handling	Do not freeze Discard if frozen Maintain cold chain as described in the “Green Book”
3.15 Advice on concurrent medication	Other concurrent vaccinations must be administered at different sites, with different syringes and needles.

4. Facilities and supplies that must be available	
4.1 Medicine to be stocked	Inactivated Hepatitis A vaccine (e.g. Avaxim®, Havrix monodose®, Epaxal®) Inactivated Hepatitis A vaccine (Junior) (e.g. Havrix Junior Monodose®, Vaqta Paediatric®)
4.2 Storage	<ul style="list-style-type: none"> • Lockable refrigerator maintained at +2 to +8°C • Maintain cold chain as described in the ‘Green Book’
4.3 Reporting incidents	<ul style="list-style-type: none"> • Incidents and near misses must be reported using the NHS Cambridgeshire Incident Reporting form (DATIX) which should be forwarded to the NHSC Risk Manager as soon as possible AND/OR • via employer’s critical incident reporting system.
4.4 Other requirements	<ul style="list-style-type: none"> • Anaphylaxis policy • Immediate access to adrenaline 1:1000 (1mg/1ml) injection • Current BNF • National guidance - Immunisation Against Infectious Disease • Supplies of relevant Patient Information Leaflets • Syringes – latex free • Needles

5. Records to be kept for audit purposes	
5.1 Patient details	<ul style="list-style-type: none"> • Patient identifiers • Allergies • Any reason for exclusion and action taken • Document patient consent or refusal • Advice sought from medical/specialist service • Details of any adverse reactions experienced by the patient and action taken • Verbal and written advice given to patient • Follow up and referral details
5.2 Records of administration	<ul style="list-style-type: none"> • Name of medicine. • Administration, date, time, route (including site of injection) and dose administered • 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, renewal of a PGD may require this to be presented as part of the update of the document • 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>
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6. References	
<ul style="list-style-type: none"> • http://emc.medicines.org.uk/ Summary of Product Characteristics, Havrix Monodose & Junior Vaccine; GlaxoSmithKline UK, updated 01 April 2009 (accessed 22 May 2010) • http://emc.medicines.org.uk/ Summary of Product Characteristics, Avaxim; SanofiPasteurMSD Ltd, updated October 2008 (accessed 22 May 2010) • http://emc.medicines.org.uk/ Summary of Product Characteristics, Epaxal; Berna Biotech Italia S.r.l. updated 13 July 2007 (accessed 22 May 2010) • http://emc.medicines.org.uk/ Summary of Product Characteristics, Vaqta Paediatric; Sanofi Pasteur MSD Ltd, updated April 2010 (accessed 22 May 2010) • Department of Health 2006: Immunisation against Infectious Disease (accessed 16 May 2010) available at http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254 • 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 • 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 Hepatitis A Vaccine for Adults and Children over 1 year

Dated:Expiry date:

BNF and SPC monographs for all drugs included in this PGD
The NHS Cambridgeshire Patient Group Direction Policy
DH Immunisation Against Infectious Diseases – The Green Book

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.