PATIENT GROUP DIRECTION (PGD)

HEPATITIS A VACCINE, INACTIVATED, ADSORBED (HAVRIX MONODOSE®)

Version:	3.0
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TURNING POINT SUBSTANCE MISUSE SERVICES

PATIENT GROUP DIRECTION (PGD) FOR:

PATIENT GROUP DIRECTION (PGD) V3 FOR

Drug: Hepatitis A vaccine, inactivated, adsorbed – Havrix Monodose®

Condition: Adults and adolescents aged 16 years and over, needing protection against Hepatitis A because of active, past or potential injecting drug use.

Professional Group: Registered Nurses

You must be Authorised by Name, Under the Current Version of this PGD before you attempt to work according to it.

Clinical Condition		
1.	**Define condition / indication**	Adults and adolescents aged 16 years and over, needing protection against Hepatitis A because of active, past or potential injecting drug use
2.	**Inclusion criteria**	• Adults and adolescents aged 16 years and over, at risk from Hepatitis A because of active or potential injecting drug use; or occupational or lifestyle risk. • Valid consent to treatment has been given by the patient.
3.	**Exclusion criteria**	• Any child under the age of 16 years. • Previous Hepatitis A infection confirmed by blood test. • Any individual who has had an anaphylactic reaction to a previous dose of Hepatitis A vaccine. • Any individual who has had an anaphylactic reaction to any of the vaccine excipients. • Hypersensitivity to any component of the vaccine • Acute severe febrile illness. The presence of minor infection is not a contraindication. • No valid consent.

4.	**Cautions / Need for further advice**	• Vaccination should be preceded by a review of previous medical history (especially with regard to previous vaccination and possible occurrence of undesirable events) • Pregnancy/breast feeding. • Liver disease. • Known or suspected exposure to hepatitis A. • As for all vaccines, appropriate medical treatment should be readily available for immediate use in case of an anaphylactic reaction following vaccination. • The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Where possible, vaccination should be postponed until immune function has recovered.
5.	**Action if excluded**	• Further explanation to gain consent, if appropriate. • Refer to GP or Clinical Lead or Deputy Clinical Lead. • Offer patient a copy of any referral letters written: document outcome of offer (acceptance or refusal) in patient notes. • In subjects with acute severe febrile illness, vaccination should be rescheduled for after the patient has recovered. • Advise about avoiding hepatitis A. • In immunosuppressed subjects, where possible, vaccination should be postponed until immune function has recovered. Otherwise, refer patient to GP or Clinical Lead or Deputy Clinical Lead.
6.	**Action if patient declines**	• Advise about protective effects of the vaccine and the risks of infection and disease complications. Document advice given. • Advise about avoiding hepatitis A infection. • Inform or refer to GP as appropriate. • Offer patient a copy of any referral letters written: document outcome of offer (acceptance or refusal) in patient notes. • Clearly document decision of patient in patient notes.

7.	**When further Medical Advice should be sought**	• If the patient is excluded from vaccination under the criteria above and postponement/rescheduling is not possible. • If the individual has been exposed to Hepatitis A infection or is in any way immunocompromised. • If an adverse reaction does occur, provide immediate treatment and inform the patient's GP as soon as possible. Discuss with the GP the need to report the reaction to CSM/MHRA using the "Yellow Card" system.
Drug Details		
8.	**Name, form and strength of medicine**	Havrix Monodose is Hepatitis A vaccine (inactivated, adsorbed) liquid suspension for injection. Each dose 1440 ELISA units per 1ml dose
	Legal Category	Prescription only medicine (POM)
	Black Triangle Status	No
	Route / method of administration	• Intra-muscular injection in the deltoid region. • subcutaneous if suffering from a bleeding disorder or taking anticoagulants.
	Dosage	1ml
	Frequency	To complete the primary course one booster dose should be given ideally 6-12 months later; this can be delayed for up to 3 yrs. If the patient remains at risk and their primary course (of two injections) was more than 20 years ago then a single booster can be given
	Total dose number to supply / administer	One or two 1ml doses as above.
9.	**Side effects**	• Adverse effects are usually mild and confined to the first few days after vaccination with spontaneous recovery. • Most commonly: mild local pain, malaise, fatigue, myalgia/arthralgia, headache, gastro-intestinal tract disorders (nausea, vomiting, decreased appetite, diarrhoea, abdominal pain), mild fever and generalised rash. • Rarely redness, soreness and/or induration at injection site and very rarely a nodule at the injection site. • Mild reversible elevation of serum transaminases has been reported on rare occasions. • Although there have been no observations of allergic or neurological manifestations following administration, such events have occurred with

9.	**Side effects continued**	related vaccines. • As with any vaccine it is possible that the use of Hepatitis A vaccine in large populations may reveal adverse effects not otherwise documented.
10.	**Reporting procedure of Adverse Reactions**	• Any serious adverse reaction to the vaccine should be documented in the patient's electronic records. The GP should also be informed. • Any serious adverse reaction to the medicine supplied / administered under this PGD should be documented in the patient's electronic treatment record. The Clinical Lead or his/her deputy should also be informed. • Any adverse events that may be attributable to the medicine supplied / administered under this PGD should be reported to the MHRA using the "Yellow Card" system (www.yellowcard.gov.uk)
11.	**Advice to patient / carer**	• The vaccine will not prevent infection caused by other agents such as hepatitis B, hepatitis C, and hepatitis E and other pathogens known to infect the liver. • Inform of the possible side effects and their management. Give advice on temperature control. • Advise about localised reaction. • At first dose, ensure patient is aware of need for booster ideally at six to twelve months. • Advise patient of requirement for hepatitis A booster vaccinations every 20 years if individual remains at risk of infection. • Advise patient/carer about avoidance of exposure to high risk of hepatitis A during two to four weeks following vaccination. • Prior to treatment, the patient should be given the Patient Information Leaflet (PIL) from the product packaging. Confirmation must be sought that they have read and understood the PIL and consent to treatment. • Recipients of any vaccine should be observed for immediate Adverse Drug Reactions. There is no evidence to support the practice of keeping patients under longer observation in the surgery. (Ref. Green Book, 2006, p.31) • If the vaccine is administered subcutaneously, the time of onset of anaphylaxis is variable and onset may be delayed for up to 72 hours. • Patients should be advised to seek urgent

		medical attention if they develop early symptoms such as breathlessness, swelling, and rash.
12.	**Arrangements for follow up**	Postponed or delayed vaccinations should be rescheduled if possible/appropriate booster to complete primary course or if remaining at risk according to antibody titre.
Referral Arrangements and Audit Trail		
13.	**Referral arrangements**	Refer to GP if excluded
14.	**Record specific information for the supply/administration of medicines to include details for audit trail and significant events**	It is essential to record the following in the patient notes:- • Patient's name/address/date of birth and consent • Indications for use • Advice given to patient/carer to (include side effects). • Brand, batch number and expiry date of medicine • Name of medicine / dose/ quantity supplied • Signed and dated. (Where computer records are used nurses must have individual identifier to enable audit trail) • Document any adverse reactions • All significant events/incidents/near misses occurring in relation to the supply / administration of a medicine under this PGD must be reported to the Senior Clinical Team and on the relevant incident form (currently Datix) in a timely manner.

Staff Characteristics	
Professional qualifications	Registered Nurse
Specialist competencies or qualifications	Knowledge of and competence in: • Basic adult life support; • Recognition and treatment of anaphylaxis; • Immunisation training and competencies; • Cold chain standards.
Continued education & training	• Annual Basic Adult Life Support training; • Turning Point approved training in the recognition and treatment of anaphylaxis ; • Training and experience in clinical assessment of the patient in order to ascertain suitability to receive the

	vaccination, according to indications listed in this PGD; • Turning Point approved training in the supply and administration of medicines under PGDs or the equivalent training in the general practice setting or other Somerset PCT commissioned service; • Individual Continued Professional Development
Additional Requirements	• There should be immediate access to Adrenaline 1:1000. • There must be access to appropriate clinical waste facilities **The health care professional-** • is professionally accountable for this work and should be working within his / her competence • should always refer to the manufacturers Summary of Product Characteristics (SPC) (available at www.medicines.org.uk) for a more complete overview of the medicine supplied / administered under this PGD. • must be authorised by name under the current version of this PGD before working under it • must be able to access this PGD when needed.
References / Resources and comments	• Current edition of *British National Formulary* (BNF). • Current edition of the *BNF for children* • Department of Health (2006) *Immunisation against infectious disease.* (The Green Book), London, Department of Health • NHS Executive (2000) *Patient Group Directions [England only]*. Health Service Circular HSC 2000/026. (Available at www.dh.gov.uk). • Nursing & Midwifery Council (2008) *Standards of Conduct, Performance and Ethics for Nurses and Midwives.* (Available at www.nmc-uk.org) • Resuscitation Council (UK) (2008) *Emergency treatment of anaphylactic reactions. Guidelines for healthcare providers* London, Resuscitation Council (UK) • Royal Pharmaceutical Society of Great Britain (2005) *The Safe & Secure Handling of Medicines: A Team Approach*. London, RPSGB. (A revision of the Duthie Report 1988) (Available at www.rpsgb.org.uk) • Summary of Product Characteristics (SPC) (Available at www.medicines.org.uk) • Turning Point Incident Reporting Policy • Turning Point Safe and Secure Handling of Medicines policy • Turning Point consent policy

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Professional Group: Registered Nurses

This patient group direction must be agreed to and signed by all health care professionals involved in its use. Turning Point should hold the original signed copy. The PGD must be easily accessible in the clinical setting	
Organisation	**TURNING POINT**

Authorisation	**Signature**	**Date**
Medical Director		10/11/14
Director of Substance Misuse		10/11/14
Lead Pharmacist		10/11/14
On behalf of Risk and Assurance		10/11/14

Director of Public Health approval for local use is required:

Name: Employing Organisation:

Signature: Date:

It is good practice to pass PGDs to local CCGs for their information, but not a legal requirement for them to approve them before use. Services are encouraged to share PDGs with local CCG Medicines Management Teams:

Local CCG name:

CCG Reviewer details:

Name: Designation:

Signature: Date:

PATIENT GROUP DIRECTION (PGD) 2.01 FOR

Drug: Hepatitis A vaccine, inactivated, adsorbed – Havrix Monodose®

Condition: Adults and adolescents aged 16 years and over, needing protection against Hepatitis A because of active, past or potential injecting drug use, or lifestyle

Professional Group: Registered Nurses

Individual Authorisation

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.
Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to supply / administer this medicine only in accordance with this PGD.

Name of Professional	Signature	Authorising Manager	Date

Please ensure a copy of this page is kept by the Line Manager.
Please return one copy to: The Clinical Lead of the service and one copy to c/o Dayella Stickland, The Substance Misuse Senior Clinical Team, Turning Point, Standon House, Mansell Street, London, E1 8AA