Patient Group Direction (PGD) for

The Administration of Combined Inactivated Hepatitis A & Hepatitis B Vaccine *(Twinrix® adult, Twinrix® paediatric)* to Adults and Children over one year by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.

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Date Uploaded & By Whom:	10/01/2013 Rebecca Stevens.

Patient Group Directions are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration under a PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

- Each PGD has a unique identifier allocated by the Prescribing Adviser responsible for the management of Patient Group Directions for the organisation.
- Once a PGD has been given approval, the date on which the PGD comes into effect will be inserted by the Prescribing Adviser prior to submission onto the NHS Rotherham intranet.
- The PGD must be reviewed within two years of authorisation
- PGDs that have failed to be reviewed and re-ratified ***must not*** be used past their expiry date and patient specific direction (prescriptions) must be used to authorise supply of medicines.

The Administration of Combined Inactivated Hepatitis A & Hepatitis B Vaccine *(Twinrix® adult, Twinrix® paediatric)* to Adults and Children over one year by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.

1. Clinical Condition or situation to which the direction applies

Drug Name: Combined Inactivated *(*Twinrix® adult, Twinrix® paediatric) Hepatitis A & Hepatitis B Vaccine.

Clinical Indications	Immunisation of adults and children aged over 1 year who are at risk of both Hepatitis A and Hepatitis B.
Criteria for Inclusion	• Valid, legal consent obtained. • Patients over one year old. • Adults at risk because of their sexual behaviour. • Injecting drug users. • Pregnancy and breast-feeding where there is a high risk of infection/exposure. • Close contacts of intravenous drug users. • Residents of homes for the mentally handicapped following local assessment. • Those with chronic liver disease.
Criteria for Exclusion	• No valid, legal consent given by the patient / carer. • Patients with known sensitivity to any component of the vaccine or previous sensitivity to Hepatitis A or Hepatitis B vaccine. • Acute febrile illness. • Pregnancy and breast-feeding if low risk of infection.

	• Children under 16 years of age with high risk sexual behaviour and/or injecting drugs. • Vaccination for travel purposes. • Not recommended for post-exposure prophylaxis following percutaneous (needle-stick), ocular or mucous membrane exposure to Hepatitis B virus. The vaccine will not prevent infection caused by Hepatitis C & E and other pathogens known to infect the liver. • Combined vaccine has not been tested in patients with impaired immunity. • Occupational Exposure: e.g. workers at risk of exposure to untreated sewage. Employers are required to undertake their own Occupational Health Risk Assessment to determine if immunisation is required through their own occupational health provider.
Action if Excluded	• Obtain legal consent • For acute febrile illness advise when vaccine may be given. • Specialist advice must be sought on the vaccines and circumstances under which they should be given. The risk to the individual of not being immunised must be taken into account. • In the case of children under 16 years old, If excluded due to high-risk sexual behaviour seek medical advice and alert to safeguarding. • Document in patient's clinical record. • Notify Child Health for under 19s. • Arrange for further appointment if needed.
Action if Patient/ Parent/Legal Guardian declines Treatment	• Advise about the protective effects of the vaccine and the risks of infection and disease complications. • Inform or refer to Medical Practitioner. • Document action and advice given in patients clinical record.
Notes for doctors / drug interactions	Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or

	symptoms to the adverse effects of the vaccine. Individuals with immunosuppression or with HIV infection (regardless of CD4 counts) should be considered for hepatitis-containing vaccines in accordance with the recommendations above. However, these individuals may not develop a full antibody response if they are immunosuppressed, and vaccine protective efficacy has not been studied. Re-immunisation should be considered after treatment is finished and recovery has occurred. Increasing the number of doses may improve the anti-HBs response in HIV-infected individuals. If rapid immunity is required then the patient should be assessed by a medical practitioner for immunoglobulin followed by a course of vaccination.

2. Description of treatment

Drug Name: Combined Inactivated Hepatitis A & Hepatitis B Vaccine (Twinrix® adult, Twinrix® paediatric)

Name, strength and formulation of drug	Inactivated Hepatitis A and rDNA Hepatitis B vaccine – Twinrix® adult (1ml pre-filled syringe) Twinrix® paediatric (0.5ml pre-filled syringe).
Legal status	POM.
Storage	Vaccines must be stored, transported and disposed according to manufacturers and the Department of Health guidelines and current legislation.
Dose/dose range	Adult-1ml (Twinrix® Adult) Child (from 1 year up to 15 years)-0.5ml (Twinrix® Paediatric)
Method /route	Intramuscular injection into deltoid region or anterolateral thigh Not to be injected into the buttock due to reduced vaccine efficacy. Subcutaneous route preferred for patients with bleeding disorders (but immune response may be reduced).
Frequency of administration	Three doses, the second 1 month after the first and third 6 months after the first. Once initiated the primary course of vaccination should be completed with the same vaccine. If monovalent vaccines are used as boosters they can be administered five years after initiation of the primary course for Hepatitis B and 10 years after initiation of Hepatitis

	A. *Accelerated schedule for intravenous drug users A schedule of three injections given at 0, 7 and 21 days. A booster is recommended 12 months after first dose. Consult PGD for individual vaccines for further information (PGDs VI 9, VI 10 and VI 13).
Total dose number	Three.
Patient/carer advice and follow-up treatment	• Inform individual about possible side effects and their management. • Give advice on temperature control *only* if patient become feverish. Whilst paracetamol and ibuprofen can lower the duration of fever and reduce distress, there is no evidence that they prevent febrile convulsions. It is not therefore recommended that these drugs are used routinely to prevent fever following vaccination as there is some evidence that prophylactic administration of antipyretic drugs around the time of vaccination may lower antibody responses to some vaccines. • Give advice regarding normal reaction to the injection. • Inform patient when subsequent doses are due when applicable. • Please include a copy of any patient information to be given with this medicine. (Provision of the Package Leaflet is a legal requirement). • Local reactions (pain, erythema, induration and oedema) within 48 hours after vaccination, and persisting for 1-2 days.

3. Records

1. The following records should be kept either paper or computer based
   For all vaccinations, the following information should be entered on all manual records including the Personal Child Health Record (PCHR-red book), computerised records and data collection for Child Health Information Services (CHIS):

   Records should be kept at ……. and information passed to patient and GP.
   - Complete Record of Attendance documentation and if appropriate enter on record 'Protocol fulfilled'
   - Patient's name, address, date of birth and consent given
   - Diagnosis
   - Name of medication
   - Dose given.

- Brand, Batch Number and Expiry Date (if supplied)
- Signature & name of staff who administered or supplied the medication, and also, if relevant, signature & name of staff who removed/discontinued the treatment
- Route and site of administration (record all sites of administration to allow any reactions to be related to the site of the injection
- Contact details of GP (if registered)
- Information & advice given to patient (including side effects)
- Details of any adverse drug reaction and actions taken, including documentation in the patient's medical record. Any adverse reaction must be notified to GP.
- Referral arrangements (including self care)
- Date administered / supplied
- Any serious adverse events that may be attributable to black triangled drugs ▼ should be reported via SUI trust procedure and then to the MHRA using the yellow card system.

2. **Audit Trail Data Collection**

- A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each practice/service.

- **Reconciliation**: Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient-by-patient basis
- **Storage**: Standards must be consistent with the Summary of Product Characteristics. All medication must be stored in a secure locked environment away from the direct patient care area

4. Anaphylaxis - Emergency Treatment

Before administering any medication the possibility of anaphylaxis must be discussed and documented with the patient/carer prior to administration of any medication, which may produce an anaphylactic reaction.
When giving any medication the following should always be readily available:

- Access to the patients notes
- Adrenaline (Epinephrine) 1 in 1000 for intramuscular (i.m.) injection for use in emergency (NB: **check expiry dates** regularly)
- Syringes and needles of **suitable size** and capacity for dose.
- Patient Group Direction for the Administration of Adrenaline (Epinephrine) 1 in 1000.
- Access to a telephone

PLEASE BE AWARE OF RESUSCITATION COUNCIL GUIDELINE CHANGES – Jan 2008.

Adrenaline (Epinephrine) 1 in1000 (1mg/ml)	**For intramuscular injection**	
Age	Dose	Volume
Children under 6 years	150 micrograms	0.15ml
Children 6 – 12 years	300 micrograms	0.3ml
Adults and adolescents	500 micrograms	0.5ml
These doses may be repeated if necessary at 5-minute intervals according to blood pressure, pulse and respiratory function.		
Special cautions: see BNF 3.4.3	Epinephrine/ Adrenaline	

BNF (64th edition) section 3.4.3 page 202-205.

(Updated Jan 2008)

Professional Responsibility All practitioners

- The practitioner will ensure he/she has the relevant training and is competent, including contra-indications. He/she will attend training updates as appropriate. **Details of the competency programme developed for use with this PGD must be attached (see PGD process above).**
- The practitioner will have due regard for the their Professional Conduct and Guidelines for the Administration / Supply of Medicines
- It is the responsibility of the individual practitioner to ensure that he/she has appropriate knowledge of the product prior to proceeding. Refer to the Summary of Product Characteristics (SPC) or current BNF for further details on the product.
- Each individual must have received a personal copy of the PGD and signed on the list of individual professionals who may work within this PGD (kept with master copy of this PGD)
- Must be competent in the recognition and management of anaphylaxis.
- Must have access to all relevant DH advice, including the relevant CMO letters o*r* training and competent in all aspects of immunisation including contraindications and recognition and treatment of anaphylaxis where appropriate.
- Must have access to a current copy of the BNF and *Immunisation against infectious disease* (The 'Green book') and comply with its recommendations (available on DH website – www.dh.gov.uk/greenbook) where appropriate.
- Annual attendance at the NHS Rotherham's or workplace update on resuscitation skills and the management of anaphylaxis within the community.
- Maintenance of own level of updating with evidence of continued professional development (PREP requirements).
- Regular updates in immunisation, vaccination, anaphylaxis and cardiopulmonary resuscitation where appropriate.
- To reinforce and update knowledge and skills in this area of practice, including basic resuscitation and anaphylaxis training, with particular reference to changes and national directives.
- Such practitioners that meet the above criteria for training have NHS Rotherham approval to administer/supply combined Inactivated Hepatitis A & Hepatitis B Vaccine *(Twinrix® adult*)
- in accordance with this PGD without a doctor's prescription, and with the patient's informed consent.
- Storage and handling of medicines should be carried out accordance with NHS Rotherham's Medicines Policy.
- The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicine, including those supplied under Patient Group Directions and all products other than those immediately administered must be labelled for supply to patients.

Sources: HSC 200/026 Patient Group Directions; BNF 64th Edition (Sept. 2012); Current Summary of Product Characteristics for product.
Refer to NHS Rotherham Procedure N1 Procedure for Emergency Treatment of Anaphylactic Reactions in the **Community (link http://websrv.rotherhampct.nhs.uk/?FileID=9575) UK Resuscitation Council (January 2008)**

5. Management of Patient Group Direction

Developed by:-	Name & Title	Signature	Date
Prepared and approved by: *Name and title in block capitals*			
Lead doctor/dentist			
Consultant in area concerned *Name and title in block capitals*			
Lead pharmacist	*Lisa Murray*		
Lead health professional from group who will administer/supply medicine *e.g. Sister XXXX Diabetic Nurse Specialist*			
Strategic Lead Clinical Risk, Infection Prevention & Control/Vacc & Imm	*Kathy Wakefield*		

Supply / Administration of Combined Hepatitis A and B Vaccine (Twinrix® and Twinrix® Paediatric) by Registered Nurses employed or contracted by NHS Rotherham working within GP Practices registered in Rotherham who have been certified after completing an agreed training plan.			
This Patient Group Direction for use in NHS Rotherham is authorised by us			
Job Title	**Name**	**Signed**	**Date**
Director of Public Health	*Dr. John Radford*		
Medical Director	*Dr. David Plews*		
Head of Medicines Management	*Stuart Lakin*		

The …… named below, being employees or contractee's of

NHS Rotherham based at…….*Clinic

OR GP Employer Name* ……..……..
***delete/complete as appropriate**

are authorised to administer/supply ……..
as specified under this Patient Group Direction

Register of Staff Trained and Assessed to Administer or Supply this Medicine:
(additional sheets may be attached)

"I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct".

Name of authorised practitioner	Signature of authorised practitioner	Clinical manager or GP	Signature of clinical manager or GP	Date