Patient Group Direction for the administration of Twinrix® vaccine (Hepatitis A and B)	
Title of patient group direction	PGD for the administration of hepatitis B vaccine in the form of Twinrix®.
Approved at	PGD Group
PGD approved / valid from	March 2018
Review date	January 2021
Expiry date	March 2021
Clinical area(s) where PGD applies	Sexual Health
Identified Lead for monitoring / review and contact details **(should this be where signatures are)**	Alison Chorlton
CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)	
New Document	Yes
Revised Document	No
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation	Adapted from Occupational Health PGD for use in sexual health
List of persons involved in the	Stuart Parkes Alison Chorlton

consultation process. (The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed).	Dr Ian Fairley

CLINICAL CONDITION	
Condition	Immunisation against hepatitis B in individuals over the age of 16 years in accordance with current national guidance for those at sexual risk Immunisation for Hepatitis A and B in individuals over the age of 16 years in accordance with current national guidance for those at sexual risk including: Men who have sex with men (MSM)
Inclusion criteria	• For use when monovalent hepatitis B vaccine is unavailable • Clients over 16 years who consent to receiving the hepatitis B vaccine (in the form of Twinrix®) and who are high risk including men who have sex with men..
Exclusion criteria	• Acute or febrile illness (do not postpone immunisation for minor coughs and colds unless there is systemic upset or fever >38.5°C • Known hypersensitivity to any component of the vaccine or its constituents e.g. neomycin in the past, or if has shown any signs of hypersensitivity after previous hepatitis B or A vaccine. • Confirmed anaphylactic reaction to a previous dose of hepatitis A or B vaccine or any component of the vaccine. • Individuals who refuse consent after receiving appropriate information or those not wishing to receive vaccination under the direction of a PGD • Pregnancy and breast feeding • Renal insufficiency • Thrombocytopenia or other bleeding disorder • Immunosuppression • Latex sensitivity • Individuals under the age of 16

Action if excluded	• Referral to medical practitioner/prescriber that clinical session. • As there may be occasions when a medial practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner. • Advice on risk reduction of acquiring hepatitis A, the importance of scrupulous attention to food, water, and personal hygiene should always be emphasised. • Advise on risk reduction for hepatitis B acquisition including condom use.
Action for patients not wishing to receive care under the PGD	As above

DESCRIPTION OF TREATMENT			
Name of Medicine	Hepatitis A and B vaccine (Twinrix®) containing Hepatitis A virus (inactivated) and Hepatitis B surface antigen		
Legal Classification	POM		
Licensing information	Licensed for non-immune adults and adolescents 16 years of age and above who are at risk of hepatitis A and B infection.		
	Is the medicine licensed for the intended use?	**YES**	
	Does it have a black triangle status?		**NO**
Form	Injection		
Strength	Hepatitis A 720 ELISA Units and Hepatitis B 20 micrograms contained in 1mL of suspension		
Dose	Individual injections of 1mL		
Frequency	Either of two main schedules may be recommended • 2 injections with an interval of one month followed by a third injection at six months after the first administration (0,1, and 6 months) • Three injections with an interval of one month and a fourth dose one year later (0,1,2 and 12 months) However, • In exceptional circumstances in adults (over 18 years) a schedule of 3 intramuscular injections given at 0,7 and 21 days may be used. When a schedule is used a fourth dose is recommended at 12 months after the first dose. • Booster at 5 years		
Route	Intramuscular injection preferably in the deltoid muscle. Exceptionally the vaccine may be administered		

	subcutaneously in patients with thrombocytopenia or bleeding disorders.	
Total Treatment Quantity	Hepatitis B antibody test performed at 8 weeks post 3rd dose of vaccine to assess level of protection Non-responders to a course of vaccine are offered one further course.	
Interactions with other medicines (This must include all potentially serious interactions listed in the BNF)	May be given concomitantly with other vaccines, using separate sites:- Hepatitis B immunoglobulin, haemophilus influenzae B, BCG, polio, measles, mumps, rubella, diphtheria, tetanus, pertussis and HPV vaccine. If in doubt then contact Medicines Information on ext 5960	
Adverse Reactions (This should include all the common and potentially serious adverse reactions. It is acceptable to state that the BNF should be referred to for further information)	**Local effects**: redness, swelling, soreness, bruising, hardness at injection site. **Systemic effects**: pyrexia, general tiredness Both local and systemic effects are transient. **Rarely**: Anaphylaxis See Summary of Product Characteristics For further information	**Treatment of adverse reactions** • Advise on symptom management of adverse effect • Report suspected ADR to a medical practitioner as soon as possible if clinically relevant. • Use the Yellow Card System to report ADR to the MHRA **Action for anaphylaxis** Call for help- dial 2222 Lay patient flat Administer oxygen therapy Administer 0.5mL IM adrenaline 1:1000
Advice to Patients: Written and Oral	Inform patient/carer of possible side effects and	

advice (This should include the provision of a patient information leaflet)	their management. • The patient/carer should be advised to seek medical advice in the event of a severe adverse reaction. • Where applicable, advise patient/carer when the subsequent dose is due. • When administration is postponed advise the patient when to return for vaccination. Supply marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. .
Follow up action	• Advise to seek medical advice in case of severe or unexpected adverse effects. • Maintain record of vaccine administration as below • Advise patient regarding follow up schedule needs
Storage	• The vaccine should be kept in its original container to protect form light. • The vaccine should be stored in a refrigerator between 2 and 8°C • Advice should be sought from Medicines Information if vaccines are exposed to higher (or lower) temperatures. Any vaccine that has been frozen must not be used. • Inspect visually for any foreign particulate matter and/or discolouration before administration, if these conditions exist the product should not be administered. • Shake before use.
Records to be Kept	In accordance with the NMC record keeping advice sheet, the following information should be recorded within an individual's record. • Brand name of the vaccine given in accordance with the PGD

	• Batch number and expiry date • Date and time of administration • Site of injection • Advice given to the patient • Risk assessment complete • Signature and print names and designation (in black ink) for paper records.
Audit Arrangements	As per current Trust PGD Policy
References	• NMC (2007, updated April 2010) Standards for Medicines Management • NMC Record Keeping Advice Sheet (July 2009) • The Code, Standards of conduct, performance and ethics for Nurses and Midwives (NMC March 2015) • SPC for Twinrix® accessed 15/8/17 via www.medicines.org.uk • DOH immunisation against Infectious Disease 2006 (Green Book) Last Modified 4/12/13
Competency Requirements (attach any competency frameworks / documents)	• Completion of the Trust PGD awareness session or Trust HUB e-learning. • Sexual health nurse • Clinical competence in sexual history taking. Clinical competence in the assessment of HIV transmission risk according to BASHH guidelines for PEPSE. • Knowledge base of the interactions of hepatitis A vaccination with other drugs, and other exclusions and contra-indications for issuing the above medicines. • Competence in the above will be demonstrated by the undertaking of a local clinical competency based training and assessment programme, evidenced by completion of theoretical study including e-learning and clinical experience within sexual health. • Assessment will be undertaken by the Lead

	Sexual Health nurse or designated PGD assessor, who will both be fully competent and either practising as an independent prescriber themselves, or practicing in accordance with this PGD. • Receiving clinical supervision and/or audit of case notes on an on-going basis. • Commitment to continuing professional development identified through clinical supervision and appraisal. • Evidence of continuing professional development in sexual health. • 5 study days or the equivalent in hours, of study related to the field of sexual health every 3 years. • Regular attendance and participation in the monthly educational clinical governance sessions. • Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development. Additionally practitioners: must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ("The Green Book"), and national and local immunisation programmes • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the "cold chain" • must be competent in the recognition and management of anaphylaxis • must have access to the Patient Group Direction and associated online resources

AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION OF: Hepatitis A and B vaccine (Twinrix®)			
PGD Development / Review Team – responsible for PGD content			
Title	**Name**	**Signature**	**Date**
Lead Author	Alison Chorlton		20.03.18
Clinical Director Lead Approval	Ian Fairley		21/3/18
Directorate Pharmacy Lead Approval	Paul Jackson		29/3/18
PGD Approved by the Area Prescribing Committee			
Title	**Name**	**Signature**	**Date**
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		20.04.2018
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes		23/04/18

Authorisation to work within the PGD

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

The PGD must be easily accessible in the clinical setting.

Notes to the Lead Authorising Prescribing Committee

- Do not proceed unless this document carries the signatures of the development / review team (Lead Author, Lead Clinical Director and Directorate Lead Pharmacy)
- You are responsible for fulfilling the legal requirement that a senior person from the profession ensures that only fully competent, qualified and trained professionals operate under this PGD
- Using a PGD is not a form of prescribing

Staff authorised to work under this PGD	
Ward / Department	Sexual health
Professionals to whom this Patient Group Direction applies	Registered nurses

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 when working for this Trust:

Name (Capitals)	Sign	Job Title	Authorising Manager	Date

When the review date is exceeded, this PGD ceases to be a legal document

TEMPLATE DOCUMENTATION CONTROL	
The template documentation control refers to the PGD template not the completed PGD. **Do not alter this section.**	
Author:	Jennie Booth, Lead Nurse Medicines Management Carol Belt, Principal Pharmacy Technician Stuart Parkes, Deputy Chief Pharmacist
Owner:	NMP/PGD Group
Date of issue:	February 2018
Version:	3
Approved by	NMP/PGD Group
Review date:	February 2021