

**Patient Group Direction for the administration of
Hepatitis B vaccination**

Title of patient group direction	Patient Group Direction for the administration of Hepatitis B vaccination
Approved at	NMP/PGD Group
PGD approved / valid from	September 2018
Review date	June 2021
Expiry date	September 2021
Clinical area(s) where PGD applies	York and North Yorkshire Sexual Health services
Identified Lead for monitoring / review and contact details	Alison Chorlton Lead Nurse ext 5465

**CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP
DIRECTION (PGD)**

New Document	No
Reviewed Document	Yes
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation	Current PGD due for renewal
List of persons involved in the 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).	Alison Chorlton, Lead nurse sexual health Elizabeth Clarke, Advanced Nurse Specialist Dr Ian Fairley, Consultant

CLINICAL CONDITION	
Condition	Patients presenting at clinics who are considered to be at high risk of hepatitis B infection
Inclusion criteria	<ul style="list-style-type: none"> • Men who have sex with men • Commercial Sex Workers and users of CSW • Intravenous drug users • Sexual partners of intravenous drug users • Patients from endemic regions that continue to be at risk of hepatitis B. • Partners of those with hepatitis/suspected infection • Sexual partners of those who are high risk for hepatitis B • Patients who have a high number of sexual contacts. • Age 16yrs or over • Victims of alleged sexual assault <p>For a booster injection the patient should have completed a full course of hepatitis B injections and serology should identify <10i.u.l of hepatitis B surface antibodies.</p>
Exclusion criteria	<ul style="list-style-type: none"> • Patients known to be HIV positive • Patients with acute hepatitis B infection • Patients who are hepatitis B surface antigen positive • Patients suffering febrile illness (do not postpone immunisation for minor coughs and colds unless there is systemic upset or fever > 38.5°C)

	<ul style="list-style-type: none"> • Pregnant women • Patients who are immunocompromised • Patients with a previous hypersensitivity to hepatitis B vaccine/excipients of the vaccine. • Children aged 15 and under • Patients with known clotting abnormalities • Patients with renal insufficiency, including patients undergoing haemodialysis • Patients who refuse treatment under a PGD
Action if excluded	<ul style="list-style-type: none"> • Refer to medical practitioner/prescriber that clinical session or when next available in clinic, • As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner. • Postpone vaccination until febrile illness resolves • Advise on risk reduction of contracting hepatitis
Action for patients not wishing to receive care under the PGD	<p>Advise on risk reduction of contracting hepatitis. Document in notes if patient declines.</p> <p>Refer to medical practitioner/prescriber that clinical session or when next available in clinic. As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner first and defer treatment until after this discussion.</p>

DESCRIPTION OF TREATMENT





Name of Medicine	Hepatitis B Vaccination (Engerix B)		
Legal Classification	Licensed, Prescription only Medicine (POM)		
Licensing information	HBVAXPRO is not included in this PGD		
	Is the medicine licensed for the intended use?	YES	
	Does it have a black triangle status?		NO
	Does it have a Risk Minimisation Measures (RMM) recommendation		NO
Form	Suspension for injection		
Strength	20 micrograms/mL		
Dose	<p>Single dose of 20 micrograms/mL (1mL)</p> <p>See BASHH guidance re: schedule. The most efficient regimen is the standard course but there is flexibility to offer other regimens to ensure the patient is vaccinated promptly when required.</p> <p>Standard course 0 month, 1 month, 6 months</p> <p>Accelerated course 0 month, 1 month, 2 months, 12 months</p> <p>Super accelerated course (patients aged 18years or over) 0 week, 7 days, 21 days, 12 months</p> <p>Timing of vaccination: Vaccination may be given earlier or later dependent on patient attendance. Flexibility may be required to ensure patient is adequately vaccinated.</p> <p>Booster At attendance (usually 10 years after the primary course).</p>		
Frequency	As above		
Route	Intramuscular injection into the deltoid area.		
Total Treatment Quantity	3 separate doses as per treatment schedule. (4 doses if accelerated/ super accelerated course) or 1 dose if a booster		

<p>Interactions with other medicines (This must include all potentially serious interactions listed in the BNF)</p>	<p>No clinically significant interactions</p> <p>May be given concomitantly with other vaccines, using separate sites such as hepatitis B immunoglobulin, Hepatitis A, & HPV vaccine. See Appendix 1 in British National Formulary (BNF) under hepatitis vaccination.</p> <p>If in doubt, contact Medicines Information for advice</p>	
<p>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)</p>	<p>Common: Discomfort at injection site, soreness, erythema.</p> <p>Rare: Fatigue, fever, malaise, flu like symptoms, dizziness, headache, paraesthesia, nausea and vomiting, diarrhoea, abdominal pain, myalgia, rash, pruritus, urticaria, abnormal LFTs, arthralgia.</p> <p>Very rare: Paralysis, neuropathy, neuritis, encephalitis, encephalopathy, convulsions, thrombocytopenia, Hypotension, arthritis, bronchospasm like symptoms, and anaphylaxis.</p>	<p>Treatment of adverse reactions Advise on symptom management of adverse reactions</p> <p>For other reaction consult appropriate Medical Staff.</p> <p>Document in case notes.</p> <p>Trust AIRs (Datix) form to be completed.</p> <p>Report reaction using the Yellow Card system to the Committee on Safety of Medicines.</p> <p>Anaphylaxis: Follow Trust anaphylaxis protocol.</p>

<p>Advice to Patients: Written and Oral advice (This should include the provision of a patient information leaflet)</p>	<p>Arrange follow up appointments according to regime prescribed.</p> <p>Encourage full STI screen if not already undertaken</p> <p>Inform of possible side effects of vaccine.</p> <p>Written and oral advice regarding aetiology and transmission of hepatitis B.</p> <p>Advice regarding the importance of completing the course of vaccination including post vaccination antibody titre level to assess efficacy of vaccination.</p> <p>Advice regarding safer sex in general for future sexual health.</p>
<p>Follow up action</p>	<p>Arrange follow up appointments according to regime prescribed.</p>
<p>Storage</p>	<ul style="list-style-type: none"> • Store between 2-8 ° C in a locked pharmacy fridge • May be temporarily transported in a validated cool bag
<p>Records to be Kept</p>	<ul style="list-style-type: none"> • Written/oral advice given. • Date • Drug name and strength • Batch number • Dose and form • Route of administration • Time of administration if appropriate • Advice given to patients • Signature of staff administering medicine • Details of any adverse drug reactions or side effects • Form of documentation (patients records, letters etc) • Any communication with other health care professionals • Follow up arrangements • Hepatitis B vaccination was administered

	under PGD
Audit Arrangements	As per current Trust PGD Policy
References	<p>National guidelines for the management of viral hepatitis, 2017, British Association for Sexual Health and HIV, www.bashh.org</p> <p>Nursing and Midwifery Council, The Code for nurses and midwives. March 2015 www.nmc.org.uk (refers to record keeping)</p> <p>Nursing and Midwifery Council, Standards for Medicines Management, 2007, minor updates 2015 www.nmc.org.uk</p> <p>The British National Formulary, www.bnf.org.uk</p>
Competency Requirements (attach any competency frameworks / documents)	<p>Clinically competent to administer IM injections into the deltoid muscle.</p> <p>Knowledge base to enable full discussion regarding Hepatitis B transmission and contra indications for issuing Hepatitis B vaccination.</p> <p>Completion of a local sexual health training programme for the administration of hepatitis B vaccination under PGD within sexual health services. This will require/include:</p> <p>Clinical competence in sexual history taking, the clinical assessment and screening required to enable the ability to identify patients who require hepatitis B vaccination.</p> <p>Knowledge base of the interactions of hepatitis b vaccination with other drugs, and other exclusions and contra-indications for administering hepatitis B vaccination</p> <p>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.</p> <ul style="list-style-type: none"> • 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

	<p>case notes on an ongoing basis</p> <ul style="list-style-type: none"> • Commitment to continuing professional development identified through Clinical Supervision and appraisal • Evidence of continuing professional development in sexual health • Regular attendance and participation in the monthly educational clinical governance/ <p>Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development.</p> <p>Attendance at Trust PGD awareness session or Trust HUB e-learning module and vaccination and immunisation updates/training</p>
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AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION OF: Hepatitis B vaccine			
PGD Development / Review Team – responsible for PGD content			
Title	Name	Signature	Date
Lead Author	ANISA ANON		10 7 / 18
Clinical Director Lead Approval	IAN FAIRBURN		1 / 8 / 18
Directorate Pharmacy Lead Approval	PAUL JACKSON		21 / 8 / 18
PGD Approved by the NMP/PGD Group			
Title	Name	Signature	Date
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes		24 / 8 / 18
<p>Authorisation to work within the PGD</p> <p>This patient group direction must be agreed to and signed by all health care professionals involved in its use.</p> <p>The PGD must be easily accessible in the clinical setting.</p>			

Notes to the NMP/PGD Authorising staff

- 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	
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Ward / Department	Sexual Health
Professionals to whom this Patient Group Direction applies	Qualified nurses who work within sexual health and have completed the agreed training programme

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:

[illegible]

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
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