

Administration
 PATIENT GROUP DIRECTION (PGD) FOR

HEPATITIS B VACCINE

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Clinical Condition	
Indication	Active immunisation against infections caused by Hepatitis B
Inclusion criteria	<p>Injection drug users (including intermittent) and those likely to progress to injecting</p> <p>Sexual partners of injection drug users</p> <p>Men who have sex with men. Male and female paid sex workers.</p> <p>Individuals who change sexual partners frequently or who have a high risk episode</p> <p>Victims of sexual assault presenting within 6 weeks of episode</p> <p>Individuals planning to have sexual partners in areas with intermediate or high prevalence of Hepatitis B</p> <p>Individuals presenting with needle-stick injuries</p> <p>Contacts who have had recent unprotected sex with individuals who have acute Hep B or who are surface antigen positive - also need referring for immunoglobulin HBIG.</p> <p>Non-medical staff and members of the public (eg police, binmen, care home workers) who suffer a needlestick injury</p> <p>All other indications as found in the DH immunisation against infectious diseases (Green Book) are not covered by this Patient Group Direction and require a Patient Specific Direction from a prescriber.</p>
Exclusion criteria If any of the following apply the PGD CANNOT be used and the patient must be referred to a doctor	<p>Individuals under 16 years of age</p> <p>Those who have a fever or acute systemic illness - immunisation should be postponed until they have fully recovered. Minor illnesses without fever or systemic upset are not valid reasons to postpone.</p> <p>Confirmed anaphylactic reaction to a previous dose of hepatitis B containing vaccine</p> <p>Confirmed anaphylactic reaction to any component of the vaccine.</p> <p>Individuals with a bleeding disorder – see below</p> <p>Immunosuppressed individuals</p> <p>Individuals on cortisone treatment/chemotherapy/radiotherapy</p> <p>Individuals with chronic renal failure including those on haemodialysis. These may require a higher dose of vaccine.</p> <p>Acute hepatitis B or individuals known to have markers of current (HBsAg) or past (anti-HB) infection. However, immunisation should not be delayed while awaiting any test results and testing, where clinically indicated, should be done at the same time as the first dose is given.</p>

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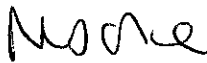
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Seek further advice from doctor, public health or Health Protection Agency and document advice and action	<p>Pregnancy and breastfeeding: Discuss with doctor and obtain Patient Specific Direction Individuals with severe latex allergy – call manufacturer to check whether the batch has any latex contamination. Individuals with a bleeding disorder should be considered for deep sub-cutaneous injection due to risk of bleeding, however the sub cutaneous route is associated with an increased risk of local reactions Check that individuals with HIV are under a specialist service</p>
Action if patient declines or is excluded	<p>Re-schedule vaccination if patient acutely unwell Document any advice given. Inform or refer to doctor as appropriate.</p>
Drug Details	
Name, form & strength of medicine	<p>Hepatitis B vaccine (inactivated) injection: HBvaxPRO, 10 microgram in 1ml Engerix B 20 microgram in 1ml Shake the vaccine well to obtain a slightly opaque, white suspension. Vaccines above are interchangeable</p>
Legal status	<p>Prescription Only Medicine (POM)</p>
Route/Method	<p>IM Injection (NOT into the buttock) Can be given at the same time as other vaccines such as Hep A, MMR, Td/IPV but at separate sites (at least 2.5cm apart), preferably different limbs.</p>
Dosage	<p>HBvaxPRO 10 microgram – 16 years and over dose 1ml Engerix B 20 microgram –16 years and over dose 1ml</p>
Frequency	<p>For Engerix B : A “very rapid schedule” for people over 18 years of age for rapid protection e.g. victims of sexual assault, injecting drug users or following a high risk episode 3 doses at 0, 7, 21 days with a booster at 12 months. Or for Engerix B and HBvaxPRO : 3 doses at zero, one and two months with a fourth dose at 12 months for those at continued risk. An alternative schedule at zero, one and six months should only be used where rapid protection is not required and there is a high likelihood of compliance. Booster dose if titre not satisfactory or after 15 years if still at risk. The recommended schedules should be followed wherever possible. It is not necessary to repeat doses if course is interrupted. Longer than recommended intervals between doses do not appear to reduce the final antibody level or efficacy.</p>

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Clinical Authorisation	
Lead Doctor	Dr Sumit Bhaduri, Consultant in GUM Signature:  Date: 3/10/16
Lead Pharmacist	Dr Alex Johnson, Senior Pharmacist in Prescribing Support Signature:  Date: 3.10.18
Organisational Authorisation	
On behalf of Worcestershire Health and Care NHS Trust	Michelle Clarke, Director of Nursing and Quality Signature:  Date: 3/10/18.

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Follow up	Antibody titre should be checked 6 -12 weeks post-immunisation.
Side effects	Soreness and redness at injection site Occasionally fever, rash malaise, influenza like syndrome, arthritis, arthralgia, and myalgia. Provide manufacturers patient information leaflet
Advice to patient/carer	Discuss the importance of completing the full vaccination course Around 10 to 15% of adults fail to respond to three doses of vaccine or respond poorly so care should be taken to avoid exposure. Advice on the control of fever. It is not recommended to use paracetamol or ibuprofen to prevent fever since this may lower response to vaccine.
Staff Characteristics	
Professional qualifications	Nurses on the NMC Register
Specialist competencies or qualifications	Has been signed up to this PGD in advance of its use by the departmental or service lead having completed online PGD training. Must be competent to undertake immunisation and vaccination and to discuss issues related to them. Has a working knowledge of, AND access to, the Department of Health Green book / website 'Immunisation against infectious diseases' and also to CMO letters regarding childhood immunisation and Vaccine Update publication. Has undertaken training in the management of anaphylaxis and resuscitation.
Continuing education & training	It is the responsibility of the individual to keep up-to-date with clinical developments as part of their continued professional development.
Referral Arrangements and Audit Trail	
Records/audit trail	That valid consent was given. Patient's name, address, date of birth, Contact details of GP (if registered). Indication. Site of administration. Batch number & Expiry date. Advice given to patient (including side effects). Signature/name of staff who gave the dose. Details of any adverse drug reaction and actions taken.
References/Resources and comments	Immunisation against Infectious Diseases and updates. Department of Health. Summary of Product Characteristics .BNF.

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Individual Authorisation

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

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. Authorising managers should be sure that staff signed up to use the PGD have the necessary competence, training and knowledge to apply it.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD. I confirm that I have the necessary competence, training and knowledge to apply it.

Name of Professional	Signature	Authorising Manager	Date

