Patient Group Direction (PGD)
For the administration of Hepatitis B vaccine by registered nurses In CRI Substance Misuse Services

PGD Details	
Indication:	To induce active immunity to Hepatitis B for patients at risk of exposure. **NB:** It can be expected that Hepatitis-D will also be prevented by immunisation against Hepatitis-B as Hepatitis-D does not occur in the absence of Hepatitis-B infection.
Lead Author's Name and Job Title:	Mohammed Fessal. Lead Pharmacist

Inclusion criteria	• Injecting drug users • The service user has previously injected drugs, so may be at risk of relapsing into this behaviour • Service user who is at risk of progressing to injecting • Non-injecting drug users of the service who are living with current injecting drug users. • Clients of the service who are sexual partners of injecting drug users, or who change their sexual partner frequently. • Service user attending the drug team, needle exchange and outreach services
Exclusion criteria If any of the following apply, the PGD CANNOT be used and the patient must be referred to a doctor	• Patient has known hypersensitivity to Hepatitis-B vaccine. • Patient has known hypersensitivity to any component of the vaccine, including aluminium. Thiomersal is not used as a preservative in hepatitis B vaccines available in the UK. However, thiomersal is still used in the production process for Engerix B®, and therefore, residues are present in the final product • Patient is known to have suffered a severe adverse reaction to a previous dose of any vaccine. • Patients known to be Hepatitis B surface antigen positive • Patients have a history of current or previous Hepatitis B infection • Already fully immunised • Current febrile illness or acute infection (minor infections without fever or systemic upset are not reasons to postpone immunisation). • Immunosuppressed or immunocompromised patients • All patients with thrombocytopenia or other bleeding disorders, or on anticoagulant therapy. • Patient is pregnant or breastfeeding • Patients with renal insufficiency including haemodialysis patients. • Patients under 18 years of age • Patient is intoxicated from drugs or alcohol • No valid consent

Action if excluded	• Refer to doctor • Record reasons, ensure any necessary follow up or referral • Provide clinically appropriate advice, in particular, regarding safe sex and not sharing injection equipment
Action if patient declines treatment	Patient to be counselled regarding the risks associated with contracting Hepatitis-B infection and the potential sources of infection. To be counselled regarding safer sex, and safer injecting techniques.

Drug Details	
Name, Form & Strength of medicine	Engerix B® Hepatitis B vaccine: (20 micrograms per ml injection)
Legal Classification (POM/P/GSL)	Prescription only medication
Route/Method of administration	• Intramuscular injection in the deltoid region **The vaccine must NOT be given into the gluteal muscle, or by intradermal or intravenous route.**
Dosage	Engerix B Hepatitis B vaccine;1ml (20 micrograms) for patients 18 years of age and over
Frequency	Vaccine frequency and total number of doses There are three schedules • 0,1 and 6 months; OR • 0,1 and 2 months; booster at 12 months; OR • 0, 7 and 21 days; booster at 12 months. The accelerated schedules should be used when protection is required more quickly, or where there may be problems with treatment compliance. Note- the accelerated schedules require a booster dose.
Booster	A single booster after 5 years may be sufficient to maintain immunity for those at continuing risk
Duration of Treatment	See above
Maximum or minimum treatment period	See above
Quantity to supply/administer	Administer single doses as above
Cautions / warnings	• Upon storage the content of the vaccine may present as a fine white deposit. This can be shaken into the liquid to leave a slightly opaque suspension suitable for injection. • Must not be used after the expiry date. • Store between temperatures +2°C and +8°C protected from light • Ensure cold chain has been maintained before and following receipt of the vaccine. • Ensure vaccine has not been frozen.
Side effects	**Adverse effects include:-** **Very Common:** soreness, erythema and induration at injection site, irritability, fatigue; **Common:** fever, headache, nausea, vomiting, diarrhoea, abdominal pain, swelling at injection site, loss of appetite **Uncommon:** flu-like symptoms, dizziness, myalgia **Rare:** arthralgia, rash, pruritis, urticaria , paraesthesia **Very rare:**

	Anaphylaxis **This list is not exhaustive please refer to SPC or BNF for full information**
Untoward events and adverse drug reactions	A patient presenting with a suspected adverse drug reactions (ADR) should be referred to a doctor if appropriate for further investigation and documented in the patient's notes. *Use the Yellow Card System to report adverse drug reactions directly to the CSM. Guidance on the use of the Yellow Card System and Yellow Cards are available in the current BNF.*
Advice to patient	• Patient Information Leaflet (where available) should be given to all patients, provide the patient with the relevant leaflet about the vaccine. • Patient is informed of the vaccine to be given, its effectiveness, and its possible adverse effects. • Patient to be advised regarding management of local reactions and to seek advice from their GP (or from the clinic), if reactions are severe. • In adults at risk, a protective efficacy between 95% and 100% has been demonstrated. • Encourage the patient to remain on the premises for at least 15 minutes after administration and remain accessible to the patient during that time.

Records and Follow Up	
Records to be kept / audit trail	A record must be maintained, in the patient's clinic notes of: • Patient name and date of birth • Consent to immunisation given by PGD • Brand of vaccine, batch number, expiry date • Date and site and dose of administration • Stage of immunisation schedule and due date of next dose • Any refusal or exclusion • Signature of immuniser • Any adverse reaction • Regular audit • Indication the vaccine has been administered under PGD
Communication with GP	• Information on vaccination should be communicated to the GP in writing ONLY if the service user consents.
Referral or further follow up action required	• Any adverse reactions to the Hepatitis B vaccination should be reported to the clinic doctor / nurse or patients GP. • Arrange follow up appointment for further immunisation as per immunisation plan. Discuss testing immune status after completing immunisation course. This is a blood test that should be offered 8 – 12 weeks after the last dose. It is particularly relevant to patients in the following groups as they may not develop sufficient immunity; • Clients in very poor general health • Immuno-compromised clients either from disease or medication. • Children of service users injecting drugs should be provided with advice and signposted to services that can provide them with hepatitis b vaccination
Monitoring arrangements for PGD	Regular audit and monitoring as determined by CRI Medicines Management Committee

Staff Characteristics	
	• Has undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in the *PGD*. • Has undertaken appropriate training for working under patient group directions for the supply and administration of medicines. • Staff must be confident to act within PGD • **YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT**
Staff Group	Registered nurse employed or contracted and authorised by CRI
Qualification required	Registered nurse who is deemed competent by CRI with relevant post registration experience and has received appropriate training and updates on resuscitation and management of anaphylaxis and demonstrates competence in this area
Special training required	1. The nurse is willing to be professionally accountable for this work. 2. The Registered Nurse must act at all times in accordance with the Nursing and Midwifery council (NMC) 'code of professional conduct' and must at all times acknowledge any limitations in their knowledge or competence. 3. Received training and is competent in all aspects of Hepatitis immunisation, including contraindications to vaccination. The nurse can demonstrate competency in giving injctions.
Continued training requirements	• Regular update on recognition of anaphylaxis • Regular update on CPR Compliance with the NMC guidelines of Post Registration Education and Practice (PREP)
Consent	Informed verbal consent must be obtained on each occasion when vaccines are being administered and recorded in the records.

Additional information applicable to vaccination	
Cold chain protocol	A system to ensure that the cold chain has not been broken during the storage of the vaccine should be in operation.
Anaphylaxis treatment	All health professionals responsible for immunisation must be familiar with techniques for resuscitation of a patient with anaphylaxis to prevent disability and loss of life.
Place of immunisation	Prior to immunisation, check- • A member of staff is able to assist the CRI Nurse • A phone line by which an ambulance can be called • Equipment for basic CPR and management of anaphylaxis including adrenaline injection must be available

References	
References consulted in drawing up this PGD	• British National Formulary- March 2014 • Summary of product characteristics September 2013 • Immunisation against infectious diseases 1996 – DoH. • NICE guidance on PGDs 2013

Managerial Content of Patient Group Direction (PGD) For the administration of Hepatitis B Vaccine by Registered Nurses in CRI Substance Misuse Services

This Patient Group Direction must be agreed to and signed by all health care professionals involved in the use. The Lead for the Clinical area operating the PGD should hold the original signed copy.

The PGD must be easily accessible in the clinical setting

Organisation	CRI

This Patient Group Direction has been authorised for use by the commissioning body	
Authorising Body	**Name:** Trudi Grant, Director of Public Health **Position:** **Sign:** **Date:** 22 February 2016

Direction Approved By:	
Clinical Director (Doctor)	**Name: Prun Bijral** **Sign:** **Date: 14/8/15**
Clinical Services Manager	**Name: Stacey Smith** **Sign:** **Date: 14/8/15**
Lead Pharmacist	**Name: Mohammed Fessal** **Sign:** **Date: 14/8/15**
Implementation date the PGD is valid from	**Date:** 12 January 2016
Expiry date this PGD is invalid after	**Date:** 14 August 2017

Review
• This Patient Group Direction is valid for **two years** from the implementation date and is subject to annual review or in line with changes in Clinical practice.

Appendix A: Health professionals' agreement to practise

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

Name of health professional	Signature	Senior representative authorising health professional	Date

Appendix A: Health professionals' agreement to practise

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

Name of health professional	Signature	Senior representative authorising health professional	Date
EILEEN KILKOYNE			27-11-15.
SHOBHA LUKE	Shobhaluke.		06-01-16

Appendix A: Health professionals' agreement to practise

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

Name of health professional	Signature	Senior representative authorising health professional	Date
EINAS KHAIR			27.11.15.
SHOBHA LUKE			06-01-16