TURNING POINT SUBSTANCE MISUSE SERVICES

Patient Group Direction (v 5.0)
for the administration of Hepatitis B vaccine given as Engerix B® or HBvaxPro® by Registered Nurses or Pharmacists working in TP premises.

Version :	5.0	
Author:	Graham Parsons	Lead Pharmacist
Approved by:	Dr David Bremner	Medical Director
Valid from:	February 2016	Review due: February 2017
Expires on:	February 2018	

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

This patient group direction has been produced by Turning Point Senior Clinical Team (Substance Misuse Directorate)

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DOCUMENT CONTROL

Document Location

Copies of this document can be obtained from:

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Revision History

The latest and master version of this document is held by the Senior Clinical Governance Team (SM) and represents the only approved copy.

REVISION DATE	ACTIONED BY	SUMMARY OF CHANGES	VERSION
February 2016	Graham Parsons	Changes to take into account comments from Public Health teams and to ensure use for service users aged 13 and over	5.0

Approvals

This document must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr David Bremner	Medical Director, Substance Misuse Directorate	February 2016	5.0
Ishbel Straker	Lead Nurse, Substance Misuse Directorate	February 2016	5.0
Mike Smith	Senior Advisor, Risk and Assurance	February 2016	5.0

Distribution

This document has been placed on IRIS for internal use only within the Substance Misuse Directorate.

Management of Patient Group Direction

Originally developed / Reviewed by:	Dr David Bremner	Medical Director, Substance Misuse
	Ishbel Straker	Lead Nurse, Substance Misuse
	Graham Parsons	Lead Pharmacist, Substance Misuse
	Michael Smith	Senior Advisor, Risk and Assurance

Date applicable:	23/02/2016
Review date:	23/02/2017
Expiry date:	23/02/2018

This Patient Group Direction has been approved for use in the AUTHORISING BODY area by:

Designation	**Name (& authorising body for local authority)**	**Signature**	**Date**
Senior Pharmacist	Graham Parsons		23/2/16
Senior Doctor	Dr David Bremner		23/2/16
Managing Director, Public Health	Mark Shepperd		23/2/16
Representative of professional group using PGD (lead nurse)	Ishbel Straker		23/2/16
Risk and Assurance, Turning Point	Michael Smith		23.2.16
Authorised Signatory at the AUTHORISING BODY	TRUDI GRANT DIRECTOR OF PUBLIC HEALTH, SCC		12/1/17

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Patient Group Direction (PGD v 5.0) for the administration of Hepatitis B vaccine given as Engerix B® or HBvaxPro® by Registered Nurses or Pharmacists working in TP premises.

Drug: Hepatitis B vaccine (Engerix B® or HBvaxPro®)

Condition: Immunisation of adults and children/adolescents 13 years or over in high risk groups for contact with hepatitis B

Professional Group: Registered Nurses *or* Pharmacists employed by Turning Point

You must be Authorised by Name, Under the Current Version of this PGD before you attempt to work according to it

Clinical Condition		
1.	**Define condition / indication**	Immunisation of adults and children/adolescents 13 years or over in high risk groups for contact with hepatitis B
2.	**Inclusion criteria**	• Adults and adolescents aged 13 years and over. • Valid consent to treatment has been given by the patient or person with parental or guardian responsibility. • Patients of the service needing protection against Hepatitis B because of: o Active, past or potential injecting drug use o Those who are likely to progress to injecting drugs e.g. those smoking heroin or crack cocaine o Patients with chronic liver disease or chronic hepatitis C infection o Individuals with multiple sexual partners o Individuals with sexually transmitted infections (STIs) and/or seeking treatment for STIs o Male and female sex workers o Men who have sex with men o Other recognised lifestyle risk o Persons with frequent or close contact with above high risk groups

3.	**Exclusion criteria**	• Any child or adolescent 12 years of age or under. • Any individual who has had an anaphylactic reaction to a previous dose a hepatitis B vaccine. • Any individual who has had an anaphylactic reaction to any of the vaccine excipients. • Hypersensitivity to any component of the vaccine • Confirmed severe latex allergy (i.e. anaphylactic reaction). HBvaxPRO® syringe plunger stopper and tip cap contain latex rubber and the manufacturers of Engerix B cannot guarantee contamination will not have occurred during the manufacturing process • Patients with chronic renal failure – different schedule and strengths may be used in this patient group. • Patients with HIV and patients with an impaired immune system may not have an adequate response to vaccination • Acute severe febrile illness. The presence of minor infection is not a contraindication. • No valid consent from patient, parent or guardian.

4.	**Cautions / Need for further advice**	• If patient is taking any other medication consult BNF Appendix 1 for any potential interactions. • Vaccination should be preceded by a review of previous medical history (especially with regard to previous vaccination and possible occurrence of undesirable events). • Vaccination may not be successful in patients who are in the incubation phase of Hepatitis B infection at the time of vaccination. • Pregnancy and breast feeding – hepatitis B infection in pregnant women may result in severe disease for mother and chronic infection of the newborn. Immunisation should not be withheld from a pregnant woman if she is in a high-risk category. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids such as hepatitis B vaccine. Since hepatitis B is an inactivated vaccine, the risks to the foetus are likely to be negligible, and it should be given when there is a definite risk of infection (Green Book, online, 2015). Neither of the vaccines included in this PGD are contraindicated in pregnancy or breastfeeding. Discussion of risk and benefits should be documented in patients' medical notes • Known or suspected exposure to hepatitis B. • Individuals receiving renal dialysis. • As for all vaccines, appropriate medical treatment should be readily available for immediate use in case of an anaphylactic reaction following vaccination. • For patients with bleeding disorders see below for details on administration • Use a product that is licensed for use in the relevant age group
5.	**Action if excluded**	• Further explanation to gain consent, if appropriate. • Refer to GP or Clinical Lead or his/her deputy to consider whether further action/advice is needed. • Offer patient, parent, or guardian a copy of any referral letters written: document outcome of offer (acceptance or refusal) in patient notes. • In subjects with acute severe febrile illness, vaccination should be rescheduled for after the patient has recovered. Document the reason for postponement in the patient notes. • Advice about avoiding hepatitis B infection.

6.	**Action if patient declines**	• Advise about protective effects of the vaccine and the risks of infection and disease complications. Document advice given in the patient's electronic record. • Advise about avoiding hepatitis B infection. • Inform or refer to GP as appropriate. • Offer patient, parent, or guardian a copy of any referral letters written: document outcome of offer (acceptance or refusal) in patient notes. • Clearly document decision of patient, parent, or person with parental responsibility in electronic patient record.
7.	**When further Medical Advice should be sought**	• If the patient is excluded from vaccination under the criteria above and postponement or rescheduling is not possible. • If patient has renal insuffiency or is undergoing renal dialysis an alternative vaccine may be appropriate. • If the individual has been exposed to hepatitis B infection • If an adverse reaction does occur, provide immediate treatment and inform the patient's GP as soon as possible. Discuss with the Clinical Lead or his/her deputy the need to report the reaction to MHRA using the "Yellow Card" system, and to report internally on Datix.

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Patient Group Direction For:

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Condition: Immunisation of adults and children/adolescents 13 years and over in high risk groups for contact with hepatitis B

Professional Group: Nurses *or* Pharmacists employed by Turning Point

Drug Details		
8.	**Name, form and strength of medicine**	Hepatitis B vaccine absorbed **Age 13 to 15 years:** • Engerix B® 20microgram/ml recombinant Hepatitis B Vaccine for injection as 10micrograms in 0.5ml vial and prefilled syringe. OR • HBvaxPRO® 5micrograms suspension for injection in 0.5ml pre-filled syringe **Age 16 years and over:** • Engerix B® 20micrograms/1ml suspension for injection as 20micrograms in 1ml vial and pre-filled syringe. OR • HBvaxPRO® 10micrograms suspension for injection in 1ml pre-filled syringe.
	Legal Category	Prescription only medicine (POM)
	Black Triangle Status	No
	Route / method of administration	Shake well before administration • Do not mix with other vaccines in the same syringe • Depending on physical and appropriate deltoid muscle development: Children and adults – intramuscular injection in the deltoid muscle. • Exceptionally the vaccine may be administered subcutaneously in patients with thrombocytopenia or bleeding disorders.

	Dosage	• Children up to and including 15 years of age: - Engerix B® 10micrograms in 0.5ml - HBvaxPRO® 5micrograms in 0.5ml • Individuals 16 years of age and over: - Engerix B® 20micrograms in 1ml - HBvaxPRO® 10micrograms in 1ml
	Frequency	Where no specific product is stated the age-appropriate dose of either Engerix B® or HBvaxPRO may be used. **Children up to and including 15 years of age:** Accelerated schedule- 3 or 4 separate doses - First dose: at an elected date - Second dose: one month later - Third dose: two months after the first dose - Fourth dose: 12 months after the first dose – only for those children who are continued risk **Children aged 16 years and over and adults at immediate risk, including injecting drug users.** Very rapid schedule- 4 separate doses (using Engerix B® 20 micrograms in 1ml) - First dose: at an elected date - Second dose: 7 days after the first dose - Third dose: 21 days after the first dose - Fourth dose: twelve months after the first dose Engerix B 20micrograms in 1ml does not have a licence for use of the very rapid schedule for patients aged 16 and 17. Nevertheless, it is regarded as a schedule that "can be used" to provide "rapid protection and to maximise compliance" and has been demonstrated to have a response "as good or better than in older adults" (Green Book, online, 2015). For this reason and its acceptance as accepted practice in the Green Book it is recommended in this PGD.
	Duration of treatment	As above
	Total dose number to supply / administer	See "frequency" (above)
9.	**Side effects**	• These are usually mild, the most common, occurring in up to half of all vaccines recipients are mild transient soreness, erythema and induration at the injection site. • Local swelling at the injection site and angioedema has been reported rarely. • Less common systemic reactions include low-grade fever,

		malaise, fatigue, arthralgia, arthritis, myalgia, headache, dizziness, syncope, nausea, vomiting, diarrhoea, abdominal pain, lymphadenopathy, abnormal LFTs and rashes rarely including urticaria. • Thrombocytopenic purpura and severe skin disorders such as erythema multiforme have exceptionally occurred. • Very rarely transient arthralgia, pruritis and urticaria have been reported appearing one week or more after injection. • Neurological manifestations occurring in temporal association have been reported with the vaccine and very rarely included paralysis, neuropathy, neuritis (including Guillain –Barre syndrome, optic neuritis and multiple sclerosis), no causal relationship has been established. • Early onset allergic-type reactions have been reported rarely. • As with any vaccine, it is possible that use in large populations will reveal adverse effects not otherwise documented
10.	**Reporting procedure of Adverse Reactions**	• Any serious adverse reaction to the vaccine should be documented in a patient's electronic record, and reported via Datix to the Clinical Governance Group. The GP should also be informed. • Any adverse events that may be attributable to vaccination should be reported to the MHRA using the "Yellow Card" system
11.	**Advice to patient / carer**	• The vaccine will not prevent infection caused by other agents such as hepatitis A, hepatitis C, and hepatitis E and other pathogens known to infect the liver. • Inform about possible side effects (pain, swelling, small painless nodule at injection site, severe allergic reactions, fever, injection site redness/bruising/rash/swelling, nausea, diarrhoea, vomiting, joint muscle pain and their management • Give advice on temperature control. Note the routine prophylactic use of ibuprofen and paracetamol is no longer recommended to prevent fever after vaccination because it may reduce response to the vaccine • Advise about localised reaction. • Advise about avoiding hepatitis B infection. • The duration of immunity is not known precisely but a single booster 5 years after the primary course may be sufficient to maintain immunity for those who continue to be at risk. • Prior to treatment, the patient or person with parental

		responsibility must be given the Patient Information Leaflet (PIL) from the product packaging. Confirmation must be sought that they have read and understood the PIL and consent to treatment. • If the vaccine is administered subcutaneously, the time of onset of anaphylaxis is variable and onset may be delayed for up to 72 hours. • Patients should be advised to seek urgent medical attention if they develop early symptoms such as breathlessness, swelling, and rash. • Recipients of any vaccine should be observed for immediate Adverse Drug Reactions. There is no evidence to support the practice of keeping patients under longer observation. (Green Book, online, 2016)
12.	**Arrangements for follow up**	• Postponed or delayed vaccinations should be rescheduled if possible/appropriate. • A booster dose may be required if the anti-HBs level is less than 100mIU/ml. Note that the Green Book only recommends testing for anti-HBs is those at risk of occupational exposure or patients with renal failure (Green Book, 2015, online). As these represent groups not covered by this PGD there is no need for anti-HB testing in TP services within the requirements of this PGD. • The duration of immunity is not known precisely but a single booster five years after the primary course may be sufficient to maintain immunity for those who continue to be at risk.

Referral Arrangements and Audit Trail		
13.	**Referral arrangements**	Refer to GP if excluded
14.	**Record specific information for the supply/administration of medicines to include details for audit trail and significant events**	It is essential to record the following in the patient notes:- • Patient's name/address/date of birth and consent • Indications for use • Route and site of administration • Date of administration • Advice given to patient/carer to (include side effects). • Brand, batch number and expiry date of medicine • Name of medicine / dose/ quantity supplied • Signed and dated. (Where computer records are used nurses/pharmacists must have individual identifier to enable audit trail) • Document any adverse reactions • All significant events/incidents/near misses occurring in relation to the supply / administration of a medicine under this PGD must be reported to the Clinical Lead or his/her Deputy, and on Datix in a timely manner.

Staff Characteristics	
Professional qualifications	Registered Nurses or Pharmacists
Specialist competencies or qualifications	Requirement as per PHE Core Curriculum for Immunisation Training 2005 • Annual resuscitation updates • Annual anaphylaxis update • Annual immunisation and vaccination updates (or sooner if deemed necessary) Knowledge of and competence in: • Basic adult and paediatric life support; • Recognition and treatment of anaphylaxis; • Immunisation training and competencies; • Cold chain standards.

Continued education & training	• Annual Basic Adult Life Support training; • Turning Point approved training in the recognition and treatment of anaphylaxis ; • Training and experience in clinical assessment of the patient in order to ascertain suitability to receive the vaccination, according to indications listed in this PGD; • Turning Point approved training in the supply and administration of medicines under PGDs or the equivalent training in the general practice setting; • Individual Continuous Professional Development
Additional Requirements	• There should be immediate access to Adrenaline 1:1000. • There must be access to appropriate clinical waste facilities • Electronic access to the current edition of the Green Book – Immunisation against Infectious Disease and any relevant updates **The health care professional-** • is professionally accountable for this work and should be working within his / her competence • should always refer to the manufacturers Summary of Product Characteristics (SPC) (available at www.medicines.org.uk) for a more complete overview of the medicine supplied / administered under this PGD. • must be authorised by name under the current version of this PGD before working under it • must be able to access this PGD when needed

References / Resources and comments	• Current edition of *British National Formulary* (BNF). • Department of Health (online) *Immunisation against infectious disease.* (The Green Book), London, Department of Health • NHS Executive (2000) *Patient Group Directions [England only].* Health Service Circular HSC 2000/026. (Available at www.dh.gov.uk). • Nursing & Midwifery Council (2008) *Standards of Conduct, Performance and Ethics for Nurses and Midwives.* (Available at www.nmc-uk.org) • Resuscitation Council (UK) (2008) *Emergency treatment of anaphylactic reactions. Guidelines for healthcare providers* London, Resuscitation Council (UK)

	• Royal Pharmaceutical Society of Great Britain (2005) *The Safe & Secure Handling of Medicines: A Team Approach*. London, RPSGB. (A revision of the Duthie Report 1988) (Available at www.rpsgb.org.uk) • Summary of Product Characteristics (SPC) (Available at www.medicines.org.uk) • Turning Point policies on Incident Reporting, Consents and Safe and Secure Handling of Medicines.

It is good practice to pass PGDs to local CCGs for their information, but not a legal requirement for them to approve them before use. Services are encouraged to share PDGs with local CCG Medicines Management Teams:

Local CCG name:

CCG Reviewer details:

Name: **Designation:**

Signature: **Date:**

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Individual Authorisation

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.

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

Name of Professional	Signature	Authorising Manager	Date

Please ensure a copy of this page is kept by the Line Manager.

Please return one copy to:

The Clinical Lead of the service and one copy to:

c/o Dayella Stickland,
The Substance issue Senior Clinical Team,
Turning Point,
Standon House,
Mansell Street,
London