Patient Group Direction
For the Administration of Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed)

This Patient Group Direction (PGD) is a specific written instruction for the administration of diphtheria, tetanus and poliomyelitis vaccine to groups of patients who may not be individually identified before presentation for treatment.

This will enable the appropriate registered healthcare professional to supply/administer treatment **in accordance with the following protocol, the recommendations of the Department of Health 1998, the codes and standards of conduct of their professional bodies and any guidelines issues by those bodies on the supply and administration of medicines**.

The majority of clinical care should be provided on an individual, patient specific basis. The supply of medicines under Patient Group Directions should be reserved for those limited situations where this offers an advantage for patients care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

Definition of clinical situation/condition	Immunisation is indicated for active immunisation against diphtheria, tetanus and poliomyelitis Young people between the ages of 10 years and 18 years who are eligible to receive a booster dose(s) of Td/IPV vaccine under the Routine Childhood Immunisation Schedule.
Name of organisation(s) within which the PGD will operate	NHS Tayside
Name(s) of clinical areas and locations where the PGD will operate	School Immunisation Teams working within Tayside schools Out of Hours Services Minor Illness and Injury Units See and Treat Services Forensic Medical Service Pharmacies
Criteria for inclusion	Age 10 years or over in patients:_ • Young adults who are eligible to receive a booster dose(s) of Td/IPV vaccine under the

	Childhood Immunisation Schedule • Whose primary immunisation against tetanus is incomplete • Whose tetanus booster course is incomplete or not up to date • Who require a booster vaccine dose as part of the schools immunisation schedule • Who are immunocompromised or whose immune status is in doubt SEE APPENDIX A
Criteria for exclusion	• Child less than 10 years of age • Patient already fully immunised (total of 5 doses of vaccine at appropriate intervals) • Patient where primary immunisation is complete, but boosters are incomplete although up to date • Tetanus prone wounds which require surgical intervention, wounds in contact with soil or manure, wounds containing foreign bodies, compound fractures, wounds or burns where patient has systemic sepsis) and patient requires tetanus immunoglobulin , injecting drug users(see appendix A) • Hypersensitivity to diphtheria, tetanus or poliomyelitis vaccines or to any other ingredient of the vaccine. • Hypersensitivity to neomycin, streptomycin or polymyxin B. These are used during production and traces may remain in the vaccine. • Acute severe febrile illness. The presence of a minor infection is not a contraindication. • Neurological complications following an earlier immunisation against diphtheria and/or tetanus.

	• Patients who are immunosuppressed • This vaccine should not be administered to pregnant women unless it is considered urgent to boost immunity. • Must be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to such subjects.
Action if excluded	Discuss reasons for no immunisation with patient Patients less than 10 years with incomplete primary immunisation history should be referred back to General Practice for immunisations as per official recommendations and/or local practice and immunisation guidelines followed. Refer to A&E if requiring tetanus immunoglobulin
Action if patient declines	Advise patients on protective effects of the vaccine and the risk of infection. Document advice given. Refer to GP
Follow up of patient e.g. hospital admission/by GP/none required	For ongoing wound care at GP practice as required.

Characteristics of staff authorised to take responsibility for the supply or administration of medicines under this patient group direction

Qualifications Required	A registered practitioner enabled to administer or supply medicines under HDL (2001) 7.
Additional Requirements	Must have undergone training in the use of PGD's and in the legal issues associated with prescribing medication under PGDs.
Continuing Training Requirements	Update in immunisation every 2 years or sooner if deemed necessary. Annual update in the recognition and treatment of anaphylaxis. Annual update on cardio-pulmonary resuscitation}, DoH (2013) guidance on Immunisations (Immunisation against Infectious Diseases – "The Green Book") {Accessed at https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book }

Profession	Nurse
Applicable professional codes and standards of conduct	NMC The Code: Professional Standards of practice & behaviour for nurses & midwives (MARCH 2015)
Applicable guidelines for supply and administration of medicines	NMC Standards for Medicines Management (November 2008)

DESCRIPTION OF TREATMENT AVAILABLE UNDER THIS PATIENT GROUP DIRECTION

Name of Medicine	Diphtheria, tetanus and poliomyelitis (inactivated) vaccine adsorbed)]
POM/P/GSL	POM
PGD Ref No	
Dose/s	The dose for children from the age of ten years, adolescents and adults is 0.5 mL
Route	Vaccine is for intramuscular injection. The recommended injection site is the deltoid region.
Total dose number	0.5 ml at any given time. Vaccine should be administered in accordance with official recommendations and/or local practice and immunisation guidelines followed.
Advice to be given to the patient	• Patients should be advised to remain in unit for at least 15 minutes following vaccination to ensure care in the event of adverse reactions. • Ensure patient or child's parent/guardian is aware of the need to complete vaccination programmes. • Make patient aware that some local discomfort at injection site may be experienced, and discuss appropriate management of symptoms. • Vertigo has been experienced by some patients following vaccination and therefore caution should be exercised when driving or operating machinery.
Identification and management of possible adverse effects	The most common events occurring after vaccine administration were local injection site reactions (pain, erythema, induration and oedema). These usually had their onset within the 48 hours following vaccination and persisted for 1 to 2 days. These reactions are sometimes accompanied by injection site nodules Vertigo has been reported following vaccination. Nausea and vomiting have been reported following vaccination. Rarely anaphylaxis – resuscitative equipment should be available

	Rarely Guillain-Barré-Syndrome has been reported after vaccination with tetanus containing vaccines. In the event of a severe adverse allergic reaction or anaphylaxis, a 999 call will be made from the school or community setting and standard measures pursued. Practitioners should follow the guidance set out in https://www.resus.org.uk/pages/reaction.pdf .
Referral for medical advice	See action if excluded information
Facilities and supplies required The designated hospital pharmacies **OR** community pharmacy are the sole procurement point for medicines	Immediate access to Epinephrine/Adrenaline 1/1000 injection for Intramuscular (IM) use. There must be easy access to a telephone in order to contact the emergency services if required Vaccine will be stored in a vaccination refrigerator with temperature controlled between 2'Cand 8 C, protected from light and not frozen. Temperatures should be recorded daily. If vaccine requires to be transported to school or community settings, the cold chain will be maintained according to the criteria identified in NHS Tayside Immunisation Policy. Resuscitation equipment including adrenaline 1/1000 injection for IM use Medication will be stored in accordance with the NHS Tayside Safe and Secure Handling of Medicines Policy.
Treatment Records	In all cases an entry in the patients medical notes should include: • Presenting complaint, relevant drug and medical history • Drug dose and quantity supplied • Date issued and by whom The Community Child Health Team will record the immunisation given to each client on the CHSP (Schools) system
Patients on concurrent medication	Vaccine may be administered at the same time as other vaccines or immunoglobulins provided that the injections are made at separate site. Patients who are taking immunosuppressive agents may not respond to vaccine.
Patient Consent	Verbal consent to treatment should be obtained prior to supplying medication
Audit Trail	In OOH, continual audit trail available through medication reconciliation records. For the Out of Hours period, electronically through Adastra system.
Adverse Reactions	All adverse reactions (actual and suspected)

	will be reported to the appropriate medical practitioner and recorded in the appropriate place (e.g. the Minor Injury Record Sheet or the Allergies and Adverse Reactions section of the General Practice Record). Where appropriate a Yellow Card Report will be forwarded to the Committee on Safety of Medicines. A supply of these forms can be found at the rear of the British National Formulary. Online reporting is available at http://yellowcard.mhra.gov.uk/

AUDIT OF PATIENT GROUP DIRECTION

Annual audit of documentation and recording of information - Who will carry this out and to whom will it be reported?	- The use of the electronic CHSP (Schools) system will facilitate the audit process. - PGD will be kept centrally within Perth, Dundee and Angus CHP • PGD will be kept in the School Nursing Service Vaccination Guidelines Box, which will be taken to each immunisation session. • - PGD will be used in Secondary Educational settings in Tayside and Designated Independent schools - To be reported to the Head of Nursing Urgent Care or SCN Out of Hours NHS Tayside
Periodic audit of clinical outcome(s) - How often will audit be carried out? - What are the audit questions? - Who will carry out the audit(s) - To whom will the audit be reported?	- To be carried out bi-annually

MANAGEMENT & MONITORING OF PATIENT GROUP DIRECTION

Developed By:

Medical Practitioner: Dr Drew Walker Signature:

Nurse: Ms Tina McMichael Signature:

Pharmacist: Mr Andrew Radley Signature:

Approved By:

Lead Clinician

Name: Signature

Tayside Area Drug & Therapeutics Committee

Name: Colin Fleming Signature:

Date Effective: **27 February 2017**

Review Date: **31 March 2019**

Plans must be made to ensure completion of a review on or by the date above. The revised PGD will then follow on immediately. If the review date is reached and no review has taken place, then the PGD will be null and void. Interim review will be required as and when new safety information comes to light.

Declaration

This protocol is authorised for use with _____
(practice/hospital etc) by the individuals named below

…… Doctor ……Date

I have read and understood this PGD and have received the specified local training to implement it effectively.

Name …….. Designation ……...

Signed …… Date ……..

Name …….. Designation ……

Signed …… Date ……..

Name …….. Designation……..

Signed …… Date ……..

Name …….. Designation ……...

Signed …… Date ……..

REGISTER OF NAMED INDIVIDUALS WHO MAY SUPPLY CARE UNDER THIS PATIENT GROUP DIRECTION

Date	Name	Qualifications

PATIENT GROUP DIRECTION TREATMENT RECORD SHEET

A treatment record sheet is required for each patient treated under a Patient Group Direction

Proforma For The Administration Of Diphtheria, tetanus and poliomyelitis (inactivated) vaccine absorbed] Under Patient Group Direction

1. PATIENT AND CONSULTATION DETAILS	
Date of Consultation	
Patient Name	
CHI	
Place of Issue	

2. PATIENT HISTORY AND EXAMINATION	
Does the patient require active immunisation against diphtheria, tetanus and poliomyelitis	Details

3. CRITERIA FOR INCLUSION
The patient may receive care under this Patient Group Direction (PGD) if she/he presents fulfills the inclusion criteria for active immunisation against diphtheria, tetanus and poliomyelitis and is 10 years or over.

4. CRITERIA FOR ABSOLUTE EXCLUSION		
The patient must be excluded from receiving treatment under this PGD, and referred to a medical practitioner as soon as possible, if one or more of the following criteria apply:		
The patient is aged less than 10 years of age	□ Yes	□ No
The patient is already fully immunised, or where primary immunisation is complete, but boosters are incomplete though up to date.	□ Yes	□ No
Wounds where risk of tetanus is high and patient requires tetanus immunoglobulin	□ Yes	□ No
The patient/carer requests to consult with a medical practitioner on this occasion	□ Yes	□ No
The patient/carer has uncertainty about the safety of the vaccine despite counselling	□ Yes	□ No
In so far as it can be ascertained the patient/carer has not given informed consent	□ Yes	□ No
The patient has a previous documented hypersensitivity to diphtheria, tetanus or poliomyelitis vaccines or to any other ingredient of the vaccine. The patient has a hypersensitivity to neomycin, streptomycin or polymyxin B (used during production and may remain in vaccine).	□ Yes	□ No
The patient has an acute febrile illness	□ Yes	□ No
The patient has neurological complications following an earlier	□ Yes	□ No

immunisation against diphtheria and/or tetanus.		
Patients is immunosuppressed	□ Yes	□ No
The patient is pregnant unless considered urgent to boost immunity.	□ Yes	□ No
Vaccine must be administered with caution to patients with bleeding disorders as bleeding may occur following intramuscular injection	□ Yes	□ No

5. CRITERIA FOR CAUTION
If the patient is taking a medicine known to interact with Vaccine

6. COUNSELLING		
Mode of action, efficacy and failure rate discussed?	□ Yes	□ No
Method and manner of administration discussed?	□ Yes	□ No
Patients should be advised to remain in unit for at least 15minutes following vaccination to ensure care in the event of adverse reactions	□ Yes	□ No
Make patient aware that some local discomfort at injection site may be experienced, and discuss appropriate management of symptoms.	□ Yes	□ No
Advise on follow up	□ Yes	□ No
Issue written information	□ Yes	□ No

7. ACTION TAKEN

Administration		
Vaccine- dose for children from the age of ten years, adolescents and adults is 0.5 ml	□ Yes	□ No
Batch number of Vaccine supplied		
Expiry date of Vaccine supplied		

Referral	
Referred to:	
Advice Given:	

8. DECLARATION

The patient/carer is unable to give written consent. He/She has given verbal consent. Practitioner's Signature: Date:

The action specified was based on the information given to me by the patient/carer, which, to the best of my knowledge, is correct Practitioner's Signature: Date:

PATIENT GROUP DIRECTION PATIENT INFORMATION SHEET

A patient information sheet has to be given to each patient treated under a Patient Group Direction

Appendix A

Tetanus Immunisation Following Injuries

Reference from DOH Green Book Revised Guidelines 2013

Immunisation Status	**Clean Wound**	**Tetanus Prone Wound** (see definition under special considerations)	
	Vaccine	*Vaccine*	Human tetanus Immunoglobulin*
Fully immunised i.e. has received a total of 5 doses of tetanus vaccine at appropriate intervals.	None required	None required	Only if high risk – (see comment asterisked * below).
Primary immunisation complete, boosters incomplete but up to date	None required (unless next dose due soon and convenient to give now)	None required (unless next dose due soon and convenient to give now)	Only if high risk - (see comment asterisked * below).
Primary immunisation incomplete or boosters not up to date	A reinforcing dose of vaccine and further doses as required to complete the recommended schedule (to ensure future immunity).	A reinforcing dose of vaccine and further doses as required to complete the recommended schedule (to ensure future immunity).	Yes: one dose of human tetanus immunoglobulin at a different site
Not immunised or immunisation status not known or uncertain	An immediate dose of vaccine followed, if records confirm this is needed, by completion of a full 5 dose course to ensure future immunity	An immediate dose of vaccine followed, if records confirm this is needed, by completion of a full 5 dose course to ensure future immunity	Yes: one dose of human tetanus immunoglobulin at a different site

***Definition of a 'High Risk' Tetanus Prone Wound:** Heavy contamination with material likely to contain tetanus spores

- Extensive devitalised tissue
- Wounds containing foreign bodies
- Compound fractures
- Wounds or burns where patient has systemic sepsis
- Injecting drug users

Tetanus prone wounds which require surgical intervention, wounds in contact with soil or manure, wounds containing foreign bodies, compound fractures, wounds or burns where patient has systemic sepsis) and patient requires tetanus immunoglobulin