Patient Group Direction For The Administration Of Human Tetanus Immunoglobulin By Nurses Working Within NHS Grampian For The Immediate Prophylaxis Of Tetanus-Prone Wounds

<table>
<thead>
<tr>
<th>Lead Author:</th>
<th>Consultation Group:</th>
<th>Approver:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines Management Specialist Nurse</td>
<td>See relevant page in the PGD</td>
<td>Medicine Guidelines and Policies Group</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature:</th>
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<tbody>
<tr>
<td>[Signature]</td>
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<table>
<thead>
<tr>
<th>Identifier:</th>
<th>Review Date:</th>
<th>Date Approved:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHSG/PGD/tet_lg/ MGPG791</td>
<td>April 2018</td>
<td>April 2016</td>
</tr>
</tbody>
</table>

A Patient Group Direction is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by Doctors, Pharmacists and other appropriate professionals, approved by the Employer and advised by the relevant professional advisory committees. In most cases, appropriate clinical care is provided on an individual basis by a specific prescriber to a specific individual patient. Patient Group Directions should only be considered where they offer a benefit to patient care without compromising patient safety in any way.

Uncontrolled when printed

Version 5
Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Approval date of PGD that is being superseded</th>
<th>Summary of Changes</th>
<th>Section heading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec 2015</td>
<td>Jan 2014</td>
<td>2 yearly update to new template</td>
<td></td>
</tr>
<tr>
<td>Dec 2015</td>
<td>Jan 2014</td>
<td>Moved information on anaphylaxis from precautions section to adverse effects.</td>
<td>Adverse effects and managing possible adverse reactions.</td>
</tr>
<tr>
<td>Dec 2015</td>
<td>Jan 2014</td>
<td>Added additional information about follow-up appointment.</td>
<td>Action if excluded.</td>
</tr>
</tbody>
</table>

Subject: Patient Group Direction
Identifier: NHSG/PGD/tet/lg/MGPG791
Replaces: NHSG/PGD/tet/lg/MGPG623
Keyword(s): PGD Patient Group Direction, Tetanus, Wound, Nurse

Policy Statement:

It is the responsibility of individual nurses and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect patient, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD as well as its dissemination. Pharmacy and Medicines Directorate is responsible for ensuring registration of this document.

Review date: At least every 2 years or sooner if current treatment recommendations change.

Document: Drafted: January 2004
Approved: April 2016, (published – May 2016)
Patient Group Direction For The Administration Of Human Tetanus Immunoglobulin By Nurses Working Within NHS Grampian For The Immediate Prophylaxis Of Tetanus-Prone Wounds

Clinical indication to which this PGD applies

<table>
<thead>
<tr>
<th>Definition of situation/condition</th>
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</thead>
<tbody>
<tr>
<td>This Patient Group Direction (PGD) will authorise nurses to administer Human Tetanus Immunoglobulin for immediate protection against tetanus in a patient with a tetanus prone wound, that has a high risk of contamination with tetanus spores, or those who have a tetanus prone wound and whose immunisation status is incomplete or unknown.</td>
</tr>
<tr>
<td>This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), The Green Book and individual Summary of Product Characteristics (SPC).</td>
</tr>
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<table>
<thead>
<tr>
<th>Inclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refer to table (<a href="#">Appendix 3</a>)</td>
</tr>
<tr>
<td>Immunosuppressed patients should be treated as if not completely immunised.</td>
</tr>
<tr>
<td>Tetanus prone-wounds include:</td>
</tr>
<tr>
<td>- Wounds or burns that require surgical intervention that is delayed for more than six hours.</td>
</tr>
<tr>
<td>- Wounds or burns that show a significant degree of devitalised tissue or a puncture-type injury, (e.g. human or animal bites) particularly where there has been contact with soil or manure.</td>
</tr>
<tr>
<td>- Wounds containing foreign bodies.</td>
</tr>
<tr>
<td>- Compound fractures.</td>
</tr>
<tr>
<td>- Wounds or burns in patients who have systemic sepsis.</td>
</tr>
<tr>
<td>If the wound, burn or injury fulfils any of the above criteria, it is considered to be high risk and therefore Human Tetanus Immunoglobulin should be given for immediate protection, irrespective of the tetanus immunisation history of the patient.</td>
</tr>
</tbody>
</table>
### Exclusion criteria
- Patient has a history of severe (i.e. anaphylactic) allergy to latex. Vaccination should be deferred until it can be ascertained that the vaccine to be used is latex-free. Check against SPC, or with Medicines Information at ARI (tel: 01224 552316). For latex allergies other than anaphylactic allergies (e.g. contact allergy to latex) vaccination may proceed as normal.
- Patients who are hypersensitive to any of the components.
- Patients who are hypersensitive to human immunoglobulin.

The lethal risk associated with tetanus rules out any potential contraindication.

Treatment of an **established** tetanus infection with Human Tetanus Immunoglobulin should only be undertaken by a doctor - **not** covered under this PGD.

### Precautions and special warnings
- Human Tetanus Immunoglobulin must not be given by intravenous injection due to the possibility of shock. Care should be taken to draw back the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel.
- Use during pregnancy and lactation - safety for use during pregnancy has not been established in controlled clinical trials. However, there is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated virus, bacterial vaccines or toxoids.
- Human Tetanus Immunoglobulin contains a small quantity of IgA. Individuals who are deficient in IgA have the potential for developing IgA antibodies and may have anaphylactic reactions after administration of blood components containing IgA. The physician must therefore weigh the benefit of treatment with Human Tetanus Immunoglobulin against the potential risk of hypersensitivity reactions.

### Referral criteria
Patients who fall into the categories detailed in the exclusion criteria.
**Action if excluded from treatment**

If a patient is excluded from treatment under this PGD, medical advice should be sought – refer to a doctor.

Give information about when the immunoglobulin may/may not be given, or give a further appointment to attend for vaccination.

The reason why the patient was excluded under the PGD will be documented in the patient’s medical notes.

**Action if patient declines treatment**

Patient should be advised of the risks and consequences of not receiving treatment.

Record outcome in Patient Medication Record if appropriate and refer the patient to their general practitioner.

**Consent**

Prior to the administration of the drug, valid consent must be obtained. Consent must be in line with current NHSG “Staff Policy for Obtaining Consent for Clinical Procedures and Healthcare Interventions”. See link below.


**Description of treatment available under the PGD**

<table>
<thead>
<tr>
<th>Name of medicine</th>
<th>Human Tetanus Immunoglobulin.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal status</td>
<td>Human Tetanus Immunoglobulin is a Prescription-only Medicine (PoM).</td>
</tr>
<tr>
<td>Form/Strength</td>
<td>Human Tetanus Immunoglobulin is an injectable medicine and is available from Bio Products Laboratory (BPL) obtained from National Services Scotland. The concentration of specific IgG to tetanus toxin is not less than 100 International Units (IU)/mL in nominal 250IU vials.</td>
</tr>
<tr>
<td>Route/Method of administration</td>
<td>Intramuscular injection into the upper arm or anterolateral thigh. Injection by deep subcutaneous route must be reserved only for individuals with a bleeding disorder (no clinical efficacy data to support administration by the subcutaneous route).</td>
</tr>
</tbody>
</table>
| **Dosage/Total Dose** | See Table, [Appendix 3](#) for patient criteria for the administration of Human Tetanus Immunoglobulin.  
Prophylaxis of tetanus-prone wounds requires a single dose of 250IU by intramuscular injection.  
A single dose of 500IU may be used in infected wounds, where surgically appropriate treatment cannot be achieved within 24 hours, and in deep or contaminated wounds with tissue damage and reduced oxygen supply, as well as foreign body injury (e.g. bites, burns, stings or gunshots). |
| **Duration of treatment** | Single injection of either 250IU or 500IU dependant on clinical presentation. |
| **Storage requirements** | Store between +2°C and +8°C.  
Do not freeze.  
Store in the original container.  
Storage of the vials at ambient temperatures (25°C) for up to one week in the original container is not detrimental.  
The vaccine should be brought to room or body temperature before use. The vaccine should be clear or slightly opalescent. Do not use solutions that are cloudy or have deposits. |
| **Follow-up (if applicable)** | Recipients should remain under observation until they have been seen to recover from the procedure. It is not possible to specify an exact length of time, but patients should remain on the premises for at least 10–15 minutes. Patients should not leave if they are feeling at all unwell without speaking to the nurse first. If necessary a doctor or the patient’s GP should be contacted for advice.  
Patients, parents or guardians may be advised that paracetamol and/or ibuprofen may be given. The directions on the bottle should be followed. If more serious adverse or persistent effects occur, the patient should be advised to contact their GP/Accident and Emergency department/NHS 24. |
| Advice to patient (Verbal) | Advice should be given on what to expect and what to do for major and minor reactions.  
Recipients should be reminded of the need for an interval of 3 months before administration of any live attenuated virus vaccine (e.g. measles, rubella, mumps, varicella). In the case of measles, this impairment may persist for up to 5 months. |
|---|---|
| Advice to patient (Written) | The patient information leaflet contained in the medicine(s) should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.  
Copies of Patient Information Leaflets and SPCs for all medicines can be found at [http://www.medicines.org.uk](http://www.medicines.org.uk) |
| Concurrent Medications/Drug Interactions | Live attenuated virus vaccines  
Immunoglobulin administration may interfere with the development of an immune response to live attenuated virus vaccines, such as rubella, mumps, and varicella, for a period of up to 3 months. After administration of this product, an interval of at least 3 months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, this impairment may persist for up to 5 months.  
**Interference with serological testing**  
After injection of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may result in misleading positive results in serological testing. Passive transmission of antibodies to erythrocyte antigens, e.g. A, B, D, may interfere with some serological tests for red cell antibodies, for example the antiglobulin test (Coombs' test). |
| Adverse effects and managing possible adverse reactions | Common side effects include local reactions such as pain, redness, swelling or tenderness may occur at the site of administration.  
Other side effects reported less commonly include; chest pain, dyspnoea, tremor, dizziness, facial oedema, glossitis, buccal ulceration, arthralgia. |
This list is not exhaustive. Please also refer to current BNF and manufacturers SPC for details of all potential adverse reactions.

BNF - [https://www.medicinescomplete.com/mc/bnf/current/](https://www.medicinescomplete.com/mc/bnf/current/)

SPCs/PILs
[https://www.medicines.org.uk/emc/](https://www.medicines.org.uk/emc/)

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report the reaction to the MHRA using the Yellow Card System. [https://yellowcard.mhra.gov.uk/](https://yellowcard.mhra.gov.uk/)

**Medical advice in cases of anaphylaxis**

Injections of IM adrenaline/epinephrine 1:1000 must be available to treat an anaphylactic reaction should this occur. Medical advice must be sought as soon as possible from a doctor if any patient develops any signs of hypersensitivity. If there is a delay in medical support arriving and the condition of the patient is deteriorating then an emergency ambulance must be called on 999 or direct via ambulance control or dial 2222 (hospital internal) according to local procedure, or seek urgent medical advice. (Refer to Patient Group Direction for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals).

### Facilities and supplies required

The following should be available at sites where the medication is to be supplied/administered:

- Appropriate storage facilities or Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit).
- An acceptable level of privacy to respect patient’s right to confidentiality and safety.
- Resuscitation equipment.
- Access to medical support (this may be via the telephone).
- Approved equipment for the disposal of used materials.
- Clean and tidy work areas.
- Copies of the current PGD for the medicine specified in the PGD.
- PGD for the administration of Adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals.
<table>
<thead>
<tr>
<th>Characteristics of staff authorised to supply/administer medicine under PGD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Professional qualifications</strong></td>
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<tr>
<td><strong>Specialist competencies</strong></td>
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<tr>
<td><strong>Ongoing training and competency</strong></td>
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<tr>
<td><strong>Professional managers/Lead Nurses will be responsible for:</strong></td>
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</table>
## Documentation

### Authorisation of administration

Nurses working within NHS Grampian can be authorised to supply/administer the drug specified in this PGD by their Nurse Manager/Consultant/practice GPs.

All authorised staff are required to read the PGD and sign the Agreement to administer Medicines under PGD ([Appendix 1](#)).

A certificate of authorisation ([Appendix 2](#)) signed by the authorising doctor/manager should be supplied. This should be held in the individual practitioners records, or as agreed locally.

### Record of administration/supply

An electronic or paper record for recording the screening of patients and the subsequent administration of the drug specified in this PGD must be completed in order to allow audit of practice. This should include:

- Name and address of patient
- Patient CHI No and date of birth
- Details of parent/guardian, or person with parental responsibility where applicable
- Consultant/General Practitioner details
- Risk group, if appropriate
- Findings of physical examination, if appropriate
- Exclusion criteria, record why drug not administered
- Reason for giving
- Consent to the administration (if not obtained elsewhere)
- Drug manufacturer, batch number and expiry date (Vaccines and injectable medicines)
- Site where drug administered, dose and route of administration
- Signature and name in capital letters of practitioner who administered the drug
- Date drug given
- Record of any adverse effects (advise patient’s doctor)
- If vaccines are given information of this administration must be provided to the GP Practice and Practitioner Services Division (PSD) for inclusion on the Scottish Immunisation Recall System (SIRS).

These records should be retained:

**For children and young people**, retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment.
**Audit**

All records the drug specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each HSCP/practice/service will be responsible for auditing completion of drug forms and collation of data.

**References**

- Electronic Medicines Compendium
  [http://www.medicines.org.uk](http://www.medicines.org.uk)

  Human Tetanus Immunoglobulin – Date of revision of text 23/11/2015, accessed 18/12/2015

- British National Formulary, 70 March 2015 – March 2016
  The Pharmaceutical Press

- Green Book Chapter 30, Tetanus

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**Management and Monitoring of Patient Group Direction**

**PGD Consultative Group**

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the of the professional group who will provide care under the direction

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mrs Frances Adamson</td>
<td>Lead Author: Medicines Management Nurse</td>
</tr>
<tr>
<td>Mrs Fiona Browning</td>
<td>Health Protection Nurse Specialist</td>
</tr>
<tr>
<td>Mrs Kirsteen Gibb</td>
<td>Ward Manager, Chalmers Hospital, Banff</td>
</tr>
<tr>
<td>Mrs Elaine Neil</td>
<td>Pharmacist, Aberdeenshire CHP Pharmacist</td>
</tr>
<tr>
<td>Dr Kathleen Targett</td>
<td>Medical Practitioner: Consultant in OHS</td>
</tr>
</tbody>
</table>
Authorising Managers

Dr Nick Fluck
Medical Director, NHS Grampian

Mr David Pfieger
Director of Pharmacy and Medicines Management, NHS Grampian

Ms Amanda Croft
Executive Director of Nursing, Midwifery and AHPs, NHS Grampian
Health Care Professional Agreement to Administer Medicines Under Patient Group Direction

I: ________________________________ (Insert name)

Working within: ________________________________ e.g. HSCP, Practice

Agree to administer medicines under the direction contained within the following Patient Group Direction

**Patient Group Direction For The Administration Of Human Tetanus Immunoglobulin By Nurses Working Within NHS Grampian For The Immediate Prophylaxis Of Tetanus-Prone Wounds**

I have completed the appropriate training to my professional standards enabling me to administer medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor outwith the recommendations of the Patient Group Direction.

Signed: __________________________________________

Print Name: __________________________________________

Date: __________________________________________

Professional Registration No: ____________________________
Certificate Of Authorisation To Administer Medicines Under Patient Group Direction

This authorises: ______________________________________

Working within: ______________________________________ e.g. HSCP, Practice

To administer medicines under the following Patient Group Direction

**Patient Group Direction For The Administration Of Human Tetanus Immunoglobulin By Nurses Working Within NHS Grampian For The Immediate Prophylaxis Of Tetanus-Prone Wounds**

The above named person has satisfied the training requirements and is authorised to administer medicines under the above Patient Group Direction. The above named person has agreed not to act beyond their professional competence nor outwith the recommendations of the Patient Group Direction

Signed: _________________________________ Authorising Manager/Doctor

Print Name: ________________________________

Date: ________________________________
### Immunisation Recommendations For Clean And Tetanus-Prone Wounds. Green Book Chapter 30, Updated April 2013.

<table>
<thead>
<tr>
<th>IMMUNISATION STATUS</th>
<th>CLEAN WOUND</th>
<th>TETANUS-PRONE WOUND</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fully immunised, i.e. has received a total of five doses of vaccine at appropriate intervals</td>
<td>None required</td>
<td>None required</td>
</tr>
<tr>
<td>Primary immunisation complete, boosters incomplete but up to date</td>
<td>None required (unless next dose due soon and convenient to give now)</td>
<td>None required (unless next dose due soon and convenient to give now)</td>
</tr>
<tr>
<td>Primary immunisation incomplete or boosters not up to date</td>
<td>A reinforcing dose of vaccine and further doses as required to complete the recommended schedule (to ensure future immunity)</td>
<td>A reinforcing dose of vaccine and further doses as required to complete the recommended schedule (to ensure future immunity)</td>
</tr>
<tr>
<td>Not immunised or immunisation status not known or uncertain</td>
<td>An immediate dose of vaccine followed, if records confirm the need, by completion of a full five-dose course to ensure future immunity</td>
<td>An immediate dose of vaccine followed, if records confirm the need, by completion of a full five-dose course to ensure future immunity</td>
</tr>
</tbody>
</table>

**Notes:**

Patients who are immunosuppressed may not be adequately protected against tetanus, despite having been fully immunised. They should be managed as if they were incompletely immunised.

<sup>1</sup> High risk is regarded as heavy contamination with material likely to contain tetanus spores and/or extensive devitalised tissue.