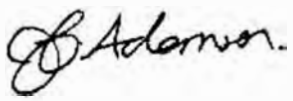
NHS Grampian

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

Lead Author: Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** Medicines Guidelines and Policies Group **Authorisation:** NHS Grampian
Signature: 		**Signature:** 
NHSG Identifier: NHSG/PGD/TIG/ MGPG1310	**Review Date:** September 2024 **Expiry Date:** September 2025	**Date Approved:** September 2022

NHS Grampian have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 7

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NHSG/PGD/TIG/MGPG942	
Date of change	**Summary of Changes**	**Section heading**
May 2022	PGD Review	
July 2022	Addition of information regarding those who have received a tetanus vaccine within the last 10 years.	Inclusion criteria
July 2022	Addition of exclusion for those who have received a tetanus vaccine within the last 10 years	Exclusion criteria

NHGS Identifier: NHSG/PGD/TIG/MGPG1310
Keyword(s): PGD Patient Group Direction Tetanus, Wound, Nurse

Policy Statement:
It is the responsibility of the individual healthcare professionals 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 individual, 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 and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	May 2022
	Completed:	July 2022
	Approved:	September 2022 (published – October 2022
	Amended & reauthorised:	

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Dawn Tweedie **Title:** Medical Director Fraserburgh Hospital **Contact email:** dawn.tweedie@nhs.scot **Signature** ..... **Date:** 30/09/2022
Senior representative of the professional group who will provide care under the direction.	**Name:** Jackie Leggat **Title:** Senior Charge Nurse **Contact email:** jackie.leggat@nhs.scot **Signature** ..... **Date:** 12/10/2022
Lead author	**Name:** Frances Adamson **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature** ..... **Date:** 27/09/2022
Pharmacist	**Name:** Elaine Neil **Title :** Lead Pharmacist H&SCP **Contact email:** elaine.neil@nhs.scot **Signature** ..... **Date:** 11/10/2022

Approved and authorised for use within NHSG by;

Medicines Guidelines and Policies Group Chair	Signature	Date Signed
Lesley Coyle		27/09/2022

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 professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse
Elaine Neil	**Pharmacist:** Lead Pharmacist, Aberdeenshire H&SCP
Dr Dawn Tweedie	**Medical Practitioner:** Medical Director Fraserburgh Hospital
Jackie Leggat	**Senior Representative:** Senior Charge Nurse, Fraserburgh Minor Injuries Unit
Fiona Browning	Health Protection Nurse Specialist
Catherine Noble	Operational Lead Nurse, Aberdeenshire H&SCP

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

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise nurses to administer Human Tetanus Immunoglobulin (TIG) for immediate protection against tetanus in individuals 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. (See Appendix 3 for guidance on the use of TIG for management of individuals following injury). This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book Chapter 30 and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	**Note:** Individual risk assessment is required and this list is not exhaustive e.g. a wound from discarded needle found in a park may be a tetanus-prone injury but a needle stick injury in a medical environment is not. Individuals who present with a high-risk tetanus-prone wound who have received an adequate priming course of tetanus vaccine but last dose more than 10 years ago. **Or** Individuals who present with a tetanus prone wound or high-risk tetanus prone wound and whose immunisation status is incomplete or unknown. **Tetanus-prone wounds include:** • Puncture-type injuries acquired in a contaminated environment and likely therefore to contain tetanus spores, e.g. gardening injuries • Wounds containing foreign bodies • Compound fractures • Wounds or burns with systemic sepsis • Certain animal bites and scratches - although smaller bites from domestic pets are generally puncture injuries animal saliva should not contain tetanus spores unless the animal has been rooting in soil or lives in an agricultural setting.

	High-risk tetanus-prone wounds include any of the above with either: • Heavy contamination with material likely to contain tetanus spores e.g. soil, manure • Wounds or burns that show extensive devitalised tissue • Wounds or burns that require surgical intervention that is delayed for more than six hours are high risk even if the contamination was not initially heavy. Prior to the administration of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current NHS Grampian consent policy.
Exclusion criteria	Individuals: • With a tetanus-prone wound who have previously received an adequate priming course (defined in relation to tetanus prone wounds as having received at least 3 doses of tetanus vaccine at appropriate intervals)***** • Who have received an adequate priming course of tetanus vaccine with the last dose within 10 years • Who have had an anaphylactic reaction to previous dose of tetanus immunoglobulin or to any of its excipients • Who have a hypersensitivity to human immunoglobulins. Individuals for whom no valid consent has been received. ***** This definition of 'adequate course' is for the risk assessment of tetanus-prone wounds only. The full UK schedule is five doses of tetanus containing vaccine at appropriate intervals.
Precautions and special warnings	TIG 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. TIG may be given to pregnant women when protection is required without delay. The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected. 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. 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.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Inform/refer to the relevant medical practitioner if individual/parent/carer declines treatment. Document that the administration was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	Human Tetanus Immunoglobulin (TIG) 100IU/mL sterile solution for injection. TIG contains human protein, 40-180 g/L of which at least 95% is IgG. The concentration of specific IgG to tetanus toxin is not less than 100IU/mL in nominal 250 IU vials.
Legal status	Human Tetanus Immunoglobulin (TIG) is a Prescription-only Medicine (POM).
Is the use out with the SmPC?	No
Dosage/Maximum total dose	Tetanus-prone or high risk tetanus prone wound one 250 IU dose, unless more than 24 hours have elapsed since injury or there is a risk of heavy contamination or following burns, in these cases the dose should be 500 IU.
Frequency of dose/Duration of treatment	Single dose of either 250 IU or 500 IU dependant on clinical presentation.
Maximum or minimum treatment period	N/A

Route/Method of administration	TIG should be administered via the intramuscular route. Ensure that TIG is not administered into a blood vessel, due to the risk of shock. The product should be brought to room or body temperature before use. If a large volume (> 2mL for children or > 5 mL for adults) is required, it is recommended to administer this in divided doses at different sites. When simultaneous vaccination is necessary, TIG and the vaccine should be administered at two different sites. If intramuscular administration is contra-indicated (bleeding disorders), the injection can be administered subcutaneously. However, it should be noted that there are no clinical efficacy data to support administration by the subcutaneous route. TIG should be brought to room or body temperature before use. The colour can vary from colourless to pale-yellow and is either clear or slightly opalescent. Do not use solutions that are cloudy or have deposits.
Quantity to be administered	250IU by intramuscular (IM) injection, or 500IU if more than 24 hours have elapsed since injury, there is a risk of heavy contamination or following burns.
Storage requirements	Medicine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Do not freeze. Store in original packaging in order to protect from light. NHSG guidance on the storage, handling and cold chain in relation to medicines/vaccines must be observed. Likewise, NHSG guidance in relation to waste management and the disposal of all spent, partially spent or unused injectable medicines must also be observed.
Additional Information	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.

Follow-up (if applicable)	Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the medicine first. If necessary a doctor or the individuals GP should be contacted for advice.
Advice (Verbal)	• Advise individual/parent/carer what to expect and of the possible side effects and their management. • If serious adverse or persistent effects occur, the individual/parent/carer should be advised to contact their GP/Accident and Emergency department/NHS24. • Individuals/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/parent/carer. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.
Identifying and managing possible adverse reactions	Syncope (fainting) can occur following, or even before, any intramuscular injection especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site. Other side effects reported less commonly include; chest pain, dyspnoea, tremor, dizziness, facial oedema, glossitis, buccal ulceration, arthralgia. As with all immunoglobulins there is a very small possibility of anaphylaxis and facilities for its management must be available. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE

	SmPC/PIL/Risk Minimisation Material: Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Document in accordance with locally agreed procedures in the individual's record. Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the medicine is to be administered: • Pharmaceutical refrigerator • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to administer medicine(s) under PGD

Professional qualifications	Registered nurses as recognised by the Nursing and Midwifery Council (NMC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/parents/carers capacity to understand the nature and purpose of the medicine administration in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD. • Competent to undertake administration of the Medicine

	• Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • Competent in the handling and storage of medicines, and management of the "cold chain" • Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken NoS PGD module training on TURAS Learn • Have attended basic life support training either face to face or online and updated in-line with Board requirements • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line with Board requirements • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the medicine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD. • Have knowledge and familiarity of the following; o SmPC for the medicine(s) to be administered in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer the medicine(s) specified in this direction.

Documentation

Authorisation of administration	Nurses working within NHS Grampian can be authorised to administer the medicine specified in this PGD by their Professional Line Manager/Consultant/Practice GP. 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 professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed locally.
Record of administration	An electronic or paper record must be completed to allow audit of practice. An electronic/HEPMA record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes. If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD, it should include as a minimum: • Date and time of administration • Individuals name and CHI • Exclusion criteria, record why the medicine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route (batch number, expiry date and anatomical site where appropriate for injectable medicines) of the medicine administered • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the medicine, and who undertook the assessment of the individual's clinical suitability for the administration of the medicine • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • Individual's GP records if appropriate • Secondary Care Medical Notes • HEPMA • Occupational health systems • Individual service specific systems. Local policy should be followed with respect to sharing information with the individual's General Practitioner.

	All records should be clear, legible and contemporaneous and in an easily retrievable format.
Audit	All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Human Tetanus Immunoglobulin (Bio Products Lab) – Date of revision of text April 2022, accessed 12/05/22. British National Formulary and the British National Formulary for Children accessed 12/05/22. Department of Health (2006): Immunisation against Infectious Disease [Green Book] Chapter 30.

Appendix 1

Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) 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 the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

Appendix 2

Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Administration Of Human Tetanus Immunoglobulin By Nurses Working Within NHS Grampian For The Immediate Prophylaxis Of Tetanus-Prone Wounds
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Appendix 3

Table 30.1 Immunisation recommendations for clean and tetanus-prone wounds

Immunisation Status	Immediate treatment			Later treatment
	Clean wound[1]	Tetanus Prone	High risk tetanus prone	
Those aged 11 years and over, who have received an adequate priming course of tetanus vaccine[2] with the last dose within 10 years Children aged 5-10 years who have received priming course and pre-school booster Children under 5 years who have received an adequate priming course	None required	None required	None required	Further doses as required to complete the recommended schedule (to ensure future immunity)
Received adequate priming course of tetanus vaccine[2] but last dose more than 10 years ago Children aged 5-10 years who have received an adequate priming course but no preschool booster *Includes UK born after 1961 with history of accepting vaccinations*	None required	Immediate reinforcing dose of vaccine	Immediate reinforcing dose of vaccine One dose of human tetanus immunoglobulin[3] in a different site	Further doses as required to complete the recommended schedule (to ensure future immunity)
Not received adequate priming course of tetanus vaccine[2] *Includes uncertain immunisation status and/ or born before 1961*	Immediate reinforcing dose of vaccine	Immediate reinforcing dose of vaccine One dose of human tetanus immunoglobulin[3] in a different site	Immediate reinforcing dose of vaccine One dose of human tetanus immunoglobulin[3] in a different site	

1. Clean wound is defined as wounds less than 6 hours old, non-penetrating with negligible tissue damage.
2. At least 3 doses of tetanus vaccine. This definition of “adequate course” is for the risk assessment of tetanus-prone wounds only. The full UK schedule is five doses of tetanus containing vaccine at appropriate intervals
3. If TIG is not available, Human Normal Immunoglobulin may be used as an alternative (**N.B.** This is **NOT** covered under this PGD)
4. Green book table 30.1 Immunisation recommendations for clean tetanus-prone wounds