Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

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. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration of

Human Tetanus Immunoglobulin solution for injection

by Registered Nurses

in

Minor Injury Units

in

Powys Teaching Health Board

Version number: PGD 011-E

NB. If human tetanus immunoglobulin is in short supply do not use this PGD. Refer for medical advice.

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Reference Number: PGD 011-E
Valid from: 01/08/2023
Review date: 01/02/2026
Expiry date: 31/07/2026

Change history

Version number	Change details	Date
PGD 011	Initial issue	15/11/02
PGD 011-A	Review issue	July 2010
PGD 011-B	Review issue	08/03/13
PGD 011-C	Review issue	01/10/16
PGD 011-D	Review issue and use of updated PTHB PGD template	01/08/20
PGD 011-E	Review issue and use of updated PTHB PGD template	01/08/2023

PGD authorisation

Name	Job Title/ Organisation	Signature	Date
Senior Doctor **Dr Kate Wright**	Lead Doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	8/9/2023
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	8/7/2023
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB- Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	8/15/2023
Senior Representative of Professional Group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: claire roche FC9C4C63FC374A7...	8/15/2023

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.** The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires.

[1] This includes any relevant amendments to legislation

Training and competency of registered health professionals	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Nursing and Midwifery Council (NMC) registered nurse with a current contract of employment with Powys Teaching Health Board (PTHB). The practitioners must also fulfil the training and additional requirements detailed below. Check Appendix A: Staff accredited to use the Patient Group Direction.

Initial training	• The administration of human tetanus immunoglobulin and knowledge of its uses, contraindications and adverse effects. Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it. • must have undertaken appropriate training for working under PGDs for supply/administration of medicines. • must have completed Patient Group Directions training available via ESR or eLearning for Healthcare (e-LfH) • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions). • must be familiar with the product(s) and alert to changes in the BNF and Summary of Product Characteristics. • Must have a thorough understanding of Chapter 30 of the Green Book. • must have undertaken training appropriate to this PGD as required by local policy. • must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. • must be competent in the administration of adrenaline and have up to date Intermediate Life Support (ILS) skills. • must have access to the Patient Group Direction and associated online resources. **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Competency assessment	• Evidence of ongoing / refresher PGD training to be submitted to Line Manager annually. • Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. • Practitioners must make a self-declaration of competency on the Personal Appraisal and Development Review (PADR).

Ongoing training and competency	• Updating at least every 2 years on the use of PGDs and human tetanus immunoglobulin. • Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, ILS, with evidence of appropriate Continued Professional Development (CPD). • Compliance with all mandatory NHS training. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**
	Clinical condition or situation to which this PGD applies
Clinical condition or situation to which this PGD applies	Immediate prophylaxis after tetanus prone injuries in patients not adequately vaccinated, in patients whose immunisation status is not known with certainty and in patients with severe deficiency in antibody production or vaccinated patients with high-risk wounds. The rationale for using intramuscular tetanus immunoglobulin (IM-TIG) is to sufficiently and rapidly raise antibody levels in exposed individuals with antibody levels below the protective threshold, and who are not expected to make a sufficiently rapid memory response to vaccination. The median incubation period for tetanus is reported as 7 days but can range from 4-21 days and therefore it is important that either IM-TIG administration or active boosting occurs promptly following an exposure. Peak levels are achieved 4 days after an IM-TIG dose. In individuals who receive a vaccine booster after having completed a full primary course, a measurable increase in antibody titres has been observed as early as 4 days, and levels increase substantially from day 7. The antibody levels achieved 5-7 days after a reinforcing dose of vaccine likely exceeds the estimated antibody boost from a prophylactic dose of IM-TIG in an adult. Human tetanus immunoglobulin should be given where immediate treatment is recommended in the Green Book, Chapter 30, Tetanus, for tetanus-prone wounds.

Clinical condition or situation to which this PGD applies	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 Note: Individual risk assessment is required and this list is not exhaustive e.g. a wound from a discarded needle found in a park may be a tetanus-prone injury but a needle stick injury in a medical environment is not. 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. Thorough cleaning of wounds is essential. NB For immunosuppressed patients and those with uncertain immunisation status or born before 1961, refer to guidance in the Green Book, Chapter 30, Tetanus. These patients may be recommended human tetanus immunoglobulin for any tetanus-prone wound. IV drug users may be at risk from illicit drugs contaminated with tetanus, especially when they have sites of focal infection such as skin abscesses which may promote growth of anaerobic organisms. **If human tetanus immunoglobulin is in short supply do not use this PGD. Refer for medical advice.** If appropriate and in line with the Green Book, Chapter 30, Tetanus, Tetanus vaccine (as combined low dose diphtheria, tetanus and inactivated polio Td/IPV - Revaxis®) can be given at the same time but using a different injection site. Refer to the appropriate PGD for use of the vaccine.

	The PTHB Minor Injury and Minor Illness guidelines must be followed and antibiotic supply considered where appropriate. **It is the responsibility of the administering Nurse to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.**
Inclusion criteria	• Human tetanus immunoglobulin is required, according to the Green Book, Chapter 30, Tetanus. • Medical and drug history taken, no reason for exclusion. • Patients 2 years of age and over. • Informed consent received. • NB Refer to PTHB Consent to Treatment and Examination Policy. • In case of any doubt, contact medical team or emergency services.
Exclusion criteria (Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)	• Conditions outside of the clinical situations criteria; human tetanus immunoglobulin not recommended according to the Green Book, Chapter 30, Tetanus. • Patient or representative refuses treatment. Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "action to be taken if the patient is excluded" and "action to be taken if the patient or carer declines treatment". • Patients under the age of 2 years. • Known hypersensitivity to the active substance or to any of its excipients. • Known hypersensitivity to human immunoglobulins, especially in patients with antibodies against immunoglobulin A (IgA). • A live vaccine has been administered in the previous three weeks. The human tetanus immunoglobulin may interfere with the response to the live vaccine. • Treatment of an ***established*** tetanus infection is not covered by this PGD. • Patients with IgA deficiency (these patients may be at a greater risk of anaphylactic reactions. Seek specialist advice).

	• Patients who are pregnant or breastfeeding. • Patients who have had an allergic reaction to blood transfusions or to treatment with plasma derivatives in the past. NB. If human tetanus immunoglobulin is in short supply do not use this PGD. Refer for medical advice.
Cautions /reasons for seeking further advice from a prescriber	Seek further advice where appropriate if patient is excluded from this PGD or for patients with complex multiple pathologies, poly-pharmacy or multiple allergies. Document advice given. Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or homeopathic products (Refer to BNF/SPC for full list). Call medical cover for advice and document advice given. Patients should be sufficiently hydrated before use of immunoglobulins - Arterial and venous thromboembolic events including myocardial infarction, stroke, deep venous thrombosis and pulmonary embolism have been associated with the use of immunoglobulins. Caution should be exercised in patients with pre-existing risk factors for thrombotic events (such as hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilisation, severely hypovolemic patients, patients with diseases which increase blood viscosity), especially when higher doses of human tetanus immunoglobulin are prescribed. Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the Minor Injury Unit guidelines followed, along with PTHB safeguarding policies. Consider discussing with GP.

	Any safeguarding concerns need to be directed to Safeguarding Hub: • To generic email address: PowysTHB.Safeguarding@wales.nhs.uk And • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads
Arrangements for referral for medical advice	Contact GP for advice or refer to DGH if applicable. Document advice given.
Action to be taken if patient excluded	Record reason and seek medical advice. Explain reason and any follow-up needed to patient / carer. If appropriate refer to GP / DGH / A&E, offer alternative management if appropriate. The risk to the individual of not being given human tetanus immunoglobulin must be taken into account.
Action to be taken if patient declines treatment	Explain consequences of refusing treatment. Advise about protective effects of the human tetanus immunoglobulin and the risks of infection and disease complications. Make patient or their representative aware of alternative sources of treatment (DGH or GP/ A&E service as appropriate). Offer alternative management if appropriate. Document refusal and any advice given. Complete a Discharge Against Advice Form if appropriate. Where appropriate, complete the letter on the WPAS system and send to the GP.

Safety Information/Special Considerations:	Human tetanus immunoglobulin must not be mixed with other pharmaceutical products. Human tetanus immunoglobulin must not be given by intravenous injection due to the possibility of shock. This product is produced from the plasma of human donors. Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/ removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV) and for non-enveloped viruses such as hepatitis A and parvovirus B19 viruses. There is reassuring clinical experience regarding the lack of hepatitis A or parvovirus B19 transmission with immunoglobulins and it is also assumed that the antibody content makes an important contribution to the viral safety.

Details of the medicine	
Name, form and strength of medicine *Include ▼for black triangle medicines*	Human tetanus immunoglobulin 100 IU/ml Bio Products Laboratory Limited Sterile solution for injection. Each vial contains nominally 250 IU of human tetanus immunoglobulin. One ml contains at least 100 IU of human tetanus immunoglobulin. The potency of this biological medicinal product may vary between batches, therefore the specific human tetanus immunoglobulin potency (IU/ml) is overprinted in the vial label. Also printed on the label, 'Dose (ml)' is the actual volume required, even at the end of shelf-life, to ensure that the patient receives 250 IU.

Legal category	POM
Indicate any off-label use	If intramuscular administration is contra-indicated (bleeding disorders), the injection can be administered subcutaneously. However, there are no clinical efficacy data to support administration by the subcutaneous route.
Route/method of administration	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. Administer via the intramuscular route into a large muscle mass. If a large volume (>2ml for children or >5ml for adults) is required, it is recommended to administer this in divided doses at different sites. When simultaneous vaccination is necessary, the human tetanus immunoglobulin 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, there are no clinical efficacy data to support administration by the subcutaneous route. Ensure that human tetanus immunoglobulin is not administered into a blood vessel, because of the risk of shock. Green book advice on injection technique: • IM injections should be given with the needle at a 90º angle to the skin and the skin should be stretched, not bunched. Deep SC injections should be given with the needle at a 45º angle to the skin and the skin should be bunched, not stretched. It is not necessary to aspirate the syringe after the needle is introduced into the muscle (WHO, 2004; Plotkin and Orenstein, 2004). • Allow the human tetanus immunoglobulin to reach room or body temperature before administration. This medicinal product must not be mixed with other medicinal products. Pictorial instructions are given in the package insert and SPC.

	Check expiry date and correct product has been chosen. When opened, use immediately. Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Equipment used for administration including used vials, ampoules, or syringes, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local authority regulations and NHSE guidance in the technical memorandum 07-01: Safe management of healthcare waste and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Dose and frequency	Administer 250 IU as a single intramuscular injection. The dose may be increased to 500 IU (administered as a single intramuscular dose) if more than 24 hours have elapsed since injury, there is a risk of heavy contamination or following burns. Follow the guidance in the Green Book, Chapter 30, Tetanus and discuss with medical team where appropriate.
Quantity to be administered	Single dose of 250 IU to 500 IU. The volume that needs to be administered to give 250 IU is stated on the label.
Maximum or minimum treatment period	Single dose
Storage	The human tetanus immunoglobulin should be maintained at a temperature of between 2°C and 8°C in a dedicated vaccines refrigerator. For transportation a validated cool box with minimum/maximum thermometers or data-loggers should be used. Storage for up to one week at ambient temperatures (up to 25°C) in the unopened package is not detrimental. Do not freeze. If the human tetanus immunoglobulin has been frozen, it should be discarded. Store in the original container and protect from light.
Drug interactions	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 immunoglobulin, 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, there may be misleading results in serological testing. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk.
Identification and management of adverse reactions	Adverse reactions such as chills, headache, dizziness, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain may occur occasionally. Rarely human immunoglobulins may cause a sudden fall in blood pressure and, in isolated cases, anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration. Local reactions at administration sites: swelling, soreness, redness, induration, local heat, itching, bruising and rash. Local induration can be minimised by deep intramuscular injection. Other reported side-effects include chest pain, dyspnoea, tremor, facial oedema, glossitis and buccal ulceration. Serious side effects such as anaphylaxis have been reported rarely. This is more likely in patients who have antibodies to IgA or in patients who have had an allergic reaction to blood transfusions or treatment with plasma derivatives. This list is not exhaustive. Refer to BNF or SPC via medicines.org.uk for complete list. Any serious adverse reaction to the human tetanus immunoglobulin should be documented in the patient's medical records (and the GP informed), and in the Personal Child Health Record if appropriate. Explain patients can self-report any suspected adverse reactions directly to the MHRA.

	For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication/ vaccine/ immunoglobulin should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the yellow card reporting scheme at: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Guidance on the yellow card system is available at the back of the BNF, or using the above link. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: • Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In case of anaphylaxis:- • Refer to adrenaline (epinephrine) PGD and anaphylaxis policy • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO human tetanus immunoglobulin**. • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers All significant adverse drug reactions and any administration errors must be recorded via the Datix Once for Wales Reporting System.
Records to be kept	Record consultation details as required by local procedures. In addition, record: • Name, address and date of birth of patient. • Name and address of GP. • Medical and drug history taken, including any allergies and previous adverse events. • Any reasons for exclusion or referral, including actions taken. • Any advice received from medical cover and advice given to patient / carer. • If the patient has refused treatment, and any advice given in this circumstance. • That valid informed patient consent to treatment was obtained. Record name of representative who gave consent if appropriate.

	• That the drug is being administered in accordance with a PGD- record PGD number and version. • Record any advice given. • For administration, record: • Date, time and site of administration. • Name, form, strength and dose of drug administered. • Route of administration. • Manufacturer, batch number and expiry date. **NB. For this product it is particularly important to record the batch number to maintain the link between patient and batch.** • Details of any adverse reactions and actions taken. • All records should be clear, legible and contemporaneous. • A record of all individuals receiving treatment under this PGD should be kept for audit purposes in accordance with local policy. Up to 18 years of age forward notification of vaccination given to Child Health Department (based in Brecon hospital for under 5 years and Llandrindod hospital for school age). The record must include the printed name and signature of the healthcare professional responsible for administration/supply. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should be kept for audit purposes in accordance with local policy.

Patient information	
Written/verbal information to be given to patient or carer	Advise that no live attenuated viral vaccine (e.g. mumps, rubella, varicella) should be given for 3 months after the human tetanus immunoglobulin. In the case of measles this should be extended to 5 months. Advise that there may be misleading positive results in serological testing after injection of immunoglobulin. Advise when subsequent doses of tetanus vaccine are due if appropriate. Explain indications, contraindications and cautions. Patients should be informed about first symptoms of thromboembolic events including shortness of breath, pain and swelling of a limb, focal neurological deficits and chest pain and should be advised to contact their physician immediately upon onset of symptoms. Provide patient information leaflet and draw patient's or representative's attention to this.
Follow-up advice to be given to patient or carer	Inform individual of possible side effects and their management. Advise them to seek medical advice immediately if they have any signs of infection, unexpected reaction or other cause for concern. Contact GP via surgery or emergency on call service. In an emergency, advise the patient to contact 999.

Key references

eBNF accessed via NICE on 26/06/2023

NICE CKS Lacerations management, Revised December 2022

The Green Book Chapter 30,Tetanus updated 01/06/2022

Summary of product Characteristics (SmPC): Bio Products Laboratory Limited 14 June 2022

Public Health England- Tetanus: guidance for health professionals- Updated 30/07/2019

Appendix A Staff accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board for the named healthcare professionals below who have signed the PGD to work under it.

Practitioner: *By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct*.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Printed name of health professional	**Signature of health professional**	**Printed name of senior representative authorising health professional**	**Signature of senior representative authorising health professional**	**Date**

The authorising manager should retain a copy of the list and a copy must be sent to the Medicines Management Team, PTHB, Bronllys Hospital, Powys LD3 0LU for audit purposes.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N)	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number)_____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion Criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager, to the staff member, and to medicines management departmen(info.medicinesmanagement.powys@wales.nhs.uk), in conjunction with the PGD Appendix A authorisation sheet.

A copy of this form should also be kept by service lead in the training file.

PGD sign off sheet – review date **