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

This Patient Group Direction (PGD) must only be used by registered healthcare 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. Healthcare 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

Sodium Chloride 0.9% w/v Solution for Injection as a Flush

by registered health professionals

in Powys Teaching Health Board

Version number: PGD 0165 A

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: 0165 A
Valid from: 31/03/2024
Review date: 31/03/2026
Expiry date: 31/03/2027

Change history

Version number	Change details	Date
PGD 0165	Initial issue	31/03/2021
PGD 0165 A	Updated according to references. Formatting changes to ensure consistency with other PTHB PGDs.	31/03/2024

This Powys Teaching Health Board (PTHB) PGD is based on a template developed on behalf of the Specialist Pharmacy Service (SPS) in July 2023. The relevant SPS template PGD was for the administration of intravenous sodium chloride 0.9% as a pre or post procedure flush during imaging procedures with contrast by registered Radiographers for imaging investigations and procedures, and it has been adapted for use in PTHB.

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior Doctor **Dr Kate Wright**	Lead Doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	3/18/2024
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	3/6/2024
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB- Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	3/20/2024
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche FC9C4C63FC374A7...	3/18/2024

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

PGD adoption by the provider

Name	Job title and organisation	Signature	Date

Training and competency of registered health professionals

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working under this PGD must also be a registered healthcare professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) Practitioners must also fulfil the additional requirements listed below. Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.
Initial training	• The administration of sodium chloride 0.9% injection as a flush and knowledge of its uses, contraindications and adverse effects. • Must have successfully completed training competencies in intravenous medicines. Must be trained in ANTT principles (aseptic non touch technique). 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. Recommended training - 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 competent to assess an individual's capacity to understand the nature and purpose of the treatment and capacity to give or refuse consent to treatment • must be familiar with the product(s) and alert to changes in the BNF and Summary of Product Characteristics. • 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, AS AN APPROVED PRACTITIONER, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Competency assessment	Evidence of ongoing PGD training to be submitted to Line Manager annually. Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions. Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of the medication included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. Practitioners operating under this PGD must be assessed as competent (see Appendix A) or complete 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 sodium chloride 0.9% injection as a flush. Organisational PGD and/or medication training as required by Powys Teaching Health Board. Evidence of ongoing / refresher PGD training to be submitted to line manager annually. Compliance with all mandatory NHS training including safeguarding at the level relevant to the role (if applicable). Practitioners must ensure they are up to date with relevant clinical skills and management of anaphylaxis,

	ILS, with evidence of appropriate Continued Professional Development (CPD). If any training needs are identified these should be addressed and further training provided. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**
The decision to administer any medicine rests with the individual registered practitioner who must abide by the PGD and any associated organisation policies.	

Clinical Condition

Clinical condition or situation to which this PGD applies	To flush peripheral intravenous cannulae to maintain patency: • Following the insertion of intravenous cannulae • Before and after intravenous drug administration • When a cannula in situ is not in use NB Healthcare professionals should also refer to any relevant PTHB policies and the Peripheral IV cannula care record. **It is the responsibility of the administering healthcare professional 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	• Medical and drug history taken, no reason for exclusion • Patients who require insertion or re-siting of a peripheral intravenous cannula or who have a peripheral intravenous cannula in situ • Visual Infusion Phlebitis (VIP) Score <2 • Informed consent received from the individual or a person legally able to act on the person's behalf, 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 PGD 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 • Patient or representative refuses treatment/no valid consent. 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 section action to be taken if the individual declines treatment • Patients with severe hypernatraemia or severe hyperchloraemia • Previous documented adverse reaction (allergic, hypersensitivity or other) after administration of sodium chloride 0.9% when used as a diluent, primer, flush, injection, or infusion. • Known hypersensitivity to any constituent of the product - see Summary of Product Characteristics • Individuals with evidence of extravasation, pain, swelling, phlebitis, redness around the canula site. • Visual Infusion Phlebitis score (VIP score) of 2 or more. • Where there is suspicion that the flushing of access might dislodge a blood clot with potential to cause clinically significant embolus. • Sodium chloride 0.9% w/v solution for injection is incompatible with the intravenous medicine to be administered. NB Healthcare professionals should also refer to any relevant PTHB policies and the Peripheral IV cannula care record. Seek advice from a prescriber if patient is excluded from this PGD. Refer to action to be taken if patient excluded

Cautions /reasons for seeking further advice from a prescriber	Patients with complex multiple pathologies, poly-pharmacy or multiple allergies. Administer with caution to patients with congestive cardiac failure, children with cardio-respiratory diseases, children receiving glucocorticoids, dilutional hyponatraemia (especially in the elderly and children), hepatic cirrhosis (in children), hypertension, peripheral oedema, pulmonary oedema, reduced fluid loss (in children), pre-eclampsia, impaired renal function (or at risk of severe renal impairment), hypernatraemia, hyperchloraemia or oedema with sodium retention. NB Patients with severe hypernatraemia or severe hyperchloraemia are excluded from this PGD- see exclusion criteria. 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). 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 PTHB safeguarding policies followed. 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 appropriate medial practitioner for advice. Document advice given.
Action to be taken if patient excluded	Record reason and seek medical advice. Explain reason to patient / carer.

Action to be taken if patient declines treatment	Explain consequences of refusing treatment. Offer alternative management if appropriate. Document refusal and any advice given. Inform or refer to GP/follow local procedures as appropriate. Complete a Discharge Against Advice Form if appropriate. Complete discharge summary where appropriate on WPAS and send to GP.

Details of the Medicine

Name, form and strength of medicine	Sodium Chloride Injection BP 0.9% w/v Solution for injection Clear, colourless aqueous solution
Legal category	POM
Indicate any off-label use	N/A
Route/method of administration	Intravenous via appropriate access device. Do not use if the solution is not clear and colourless or if the container or its closure show visible signs of damage.
Dose and frequency	Adult: Up to 5-10ml as a single dose for flushing. Child: Use 2-10ml depending on the age, size and condition of the patient: - • A single dose to be administered at the time of cannulation • As a single dose before and after the administration of each intravenous medication • Up to twice a day to maintain cannula patency • The flush should be administered using a push-pause and positive pressure method. Do not use excessive force. • 10ml syringes must be used when flushing
Quantity to be administered	See above- up to 10ml via an intravenous cannula.
Maximum or minimum treatment period	See above
Storage	Do not store above 25°C.

Drug interactions	It is the responsibility of the healthcare professional to check the compatibility of the medicine with sodium chloride 0.9% injection. The concomitant use of sodium-retaining drugs, (e.g. corticosteroids, non-steroidal anti-inflammatory agents) may lead to oedema. **NB** Check the SPC via www.medicines.org.uk for a full list of interactions.
Identification, management and reporting of adverse effects	Adverse effects are unlikely due to the small volume use. Refer to BNF or SPC via www.medicines.org.uk for full details of known adverse effects. Rarely local pain and swelling associated with the infusion may occur. Extravasation may be associated with high-pressure injection and fragile or damaged veins. Although most injuries caused by extravasation are minor, severe injuries may include skin ulceration, soft tissue necrosis and compartment syndrome. Should there be any concerns about extravasation, contact a doctor. Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions 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 App in the Google Play or Apple App Store. For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication should be reported. Guidance on the yellow card system is available in the BNF, or using the above link. • Record all adverse drug reactions (ADRs) in the individual's clinical record and inform a doctor. The patient's primary care clinician should also be informed. All significant adverse drug reactions and any supply errors must be recorded via the Once for Wales Reporting System.

	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 sodium chloride 0.9% injection**. • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers Report via 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 the criteria under which the patent fits the PGD, any allergies and previous adverse events. • Individual inclusion or exclusion from PGD, 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 and actions taken 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 • Date and time of administration.

	• Name, form, strength and dose of drug administered. • Route and site of administration • Expiry date(s) • Details of any adverse reactions and actions taken. • Relevant information that was given to the individual/carer. The record must include the date and printed name and signature of the healthcare professional responsible for administration. 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	Patient information leaflet must be available to patient if required. Patient to receive appropriate advice in accordance with the medicine prescribed or procedure/condition treated. Inform the patient of the reason for the flush and obtain consent.
Follow-up advice to be given to patient or carer	Advise them to seek medical advice immediately if they have any unusual, unexpected, or life-threatening reaction or other cause for concern. Advise the individual of possible adverse effects and their management and where to seek advice in the event of a suspected adverse reaction developing. Individual should be assessed prior to being discharged from the department for any adverse effects or for any signs of extravasation.

Key references

SPC Hameln pharma Ltd. www.medicines.org.uk:
26 Jan 2023 sodium chloride injection 0.9% w/v Accessed 5/12/23

SPC B Braun 0.9% sodium chloride injection BP www.medicines.org.uk:
- 26 October 2023. Accessed 5/12/23

Electronic British National Formulary https://bnf.nice.org.uk Accessed 5/12/23

VIP Score - IVTEAM https://www.ivteam.com/vip-score/ Accessed 6/12/23

NICE Medicines practice guideline "Patient Group Directions"
https://www.nice.org.uk/guidance/mpg2

Medusa NHS Injectable Medicines Guide. Accessed 6/12/23

https://www.medusaimg.nhs.uk/?ID=24cba7ab215eddcfdaf2d0d9746dd90d2150)

Appendix A Staff accredited to use this 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 or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager must use the competency checklist (below).*

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 (Authorising Manager)**	**Signature of senior representative authorising health professional (Authorising Manager)**	**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. This list should be kept by PTHB (or the provider organisation adopting an authorised version of the PGD) for 25 years after the PGD expires.

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) Specify in "comments"	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 department (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.