This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practise under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

For the Administration of Sodium Chloride injection 0.9% as an intravenous flush for maintaining peripheral intravenous cannula patency and following administration of a bolus injection by Registered Nurses at BPAS Clinics.

Version Number 1.1

Change History	
Version and Date	Change Details
1.0 January 2023	First issue of PGD.

1.1 January 2024	• Registered midwives removed from use of PGD as administration of sodium chloride injection 0.9% as an intravenous flush is permitted under midwifery exemptions
	• Reference made to PIVC (peripheral intravenous cannula) throughout instead of intravenous cannula
	• Dose amended to 10mls as a single flush from 5 - 10mls
	• Duplication of remove/re-site IV cannula removed in actions to be taken if individual is excluded
	• Duration of treatment further clarified
	• References for Royal College of Nursing and National Infusion and Vascular Access Society added
	• Applicable updates to PGD made in line with Specialist Pharmacy Service version 1.0 PGD for intravenous sodium chloride 0.9% as a pre or post procedure flush during imaging procedures with contrast by registered radiographers. Sections updated:
	  • Informed consent added to inclusion criteria
	  • Exclusion criteria expanded
	  • Records to be kept expanded

Valid from: 16 January 2024

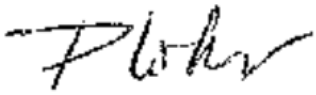
Review Date: 31 October 2025

Expiry Date: 31 January 2026

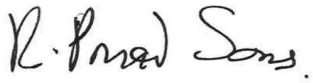
N.B. Review and update may occur prior to this period if national guidance changes or legal or clinical issues arise.

BPAS PGD Organisational Authorisations:

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

Name	Job title and organisation	Signature	Date
Vicky Garner	BPAS Consultant Midwife		16/01/2024
Patricia Lohr	BPAS Medical Director		16/01/2024
Kalpesh Thakrar	BPAS Lead Pharmacist		16/01/2024

Authorising Body:

Cheshire and Merseyside ICB	*Rowan Pritchard-Jones*		*07/11/2024*

Responsible person who has approved this PGD on behalf of BPAS

Name: Lucy Moore

Position: Executive Chair

Signature: 

Date: 16/01/2024

1. Characteristics of staff authorised to use this PGD:	
Qualifications and professional registration	• NMC Registered Nurse Practitioners must also fulfil the additional requirements listed below.

Initial training	Pharmacological knowledge relating to the administration and supply of the medicine, its uses, contraindications, dosage and adverse effects
	
	Additionally, practitioners:
	• Must have completed appropriate training for working under a PGD for the supply / administration of medicines (see training requirements in the BPAS PGD policy)
	• Must be familiar with the medicine and observant to changes in the BNF and Summary of Product Characteristics (SmPC)
	• Must be competent in the recognition and management of adverse reactions, including anaphylaxis
	• Must be competent in the administration of adrenaline for anaphylaxis and have up to date Basic Life Support (BLS) skills as a minimum
	• Must have access to the PGD and associated online resources
	• Must have undertaken post-registration intravenous (IV) administration of medicines training and be assessed as competent in the administration of IV medicines
	• Knowledge of the following BPAS policies:
	  ○ Insertion of a Peripheral Intravenous Cannula
	  ○ Administration of Parenteral Medication
	
	The practitioner must be authorised by name, under the current version and terms of this PGD in the Approved Practitioner List before working to it.

Competency Assessment	Practitioners working under this PGD are required to review their own competency using the NICE Competency Framework for Health Professionals using Patient Group Directions Practitioners working under this PGD must be assessed as competent or complete a self-declaration of competence to use this PGD (see appendix A). **Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines 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.**
Ongoing training and competency	• Practitioners must complete 3-yearly PGD Theory Refresher training and competency assessment • Practitioners working under this PGD are responsible for ensuring they remain up to date with the use of the medicines and guidance included in the PGD, ensuring any training needs identified are addressed with further training • Practitioners must make sure they are aware of any changes to the recommendations for this medication • Practitioners must ensure they remain up to date with relevant clinical skills, management of anaphylaxis, BLS (as a minimum), with evidence of continued professional development

	• Practitioners are responsible for maintaining their competency to work under this PGD, including in the administration of medicines via the IV route
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD an any associated organisational policy.	

2. Clinical condition or situation to which this PGD applies:	
Clinical condition or situation to which this PGD applies	Flushing of peripheral intravenous cannula (PIVC) to maintain patency: • Following the insertion of a PIVC • Before and after IV drug administration • When cannula PIVC is clinically indicated to remain in situ but is not in use
Inclusion criteria	• Informed consent gained • BPAS clients with cannula PIVC newly sited or already in situ
Exclusion criteria	• Consent declined • 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. • Individuals with evidence of extravasation, pain, swelling, phlebitis, redness around the canula site • Where there is suspicion that the flushing of access might dislodge a blood clot with potential to cause clinically significant embolus.
Cautions/Circumstances in which further advice should be sought from a doctor (including any relevant action to be taken)	• Examine the PIVC site prior to administering flush to exclude any signs of phlebitis • Avoid excessive administration Caution is advised and advice should be sought from a doctor in the presence of the following: • Cardiac failure • Peripheral oedema • Pre-eclampsia • Hypertension • Pulmonary oedema
Action to be taken if the individual is excluded	• Inform doctor, if clinically indicated, for further assessment • If exclusion is due to a red/swollen/inflamed injection site, remove the PIVC and only re-site it if clinically indicated • Document reasons for exclusion in the client's clinical record
Action to be taken if the individual or carer declines treatment	• Explain the rationale for the flush and any potential effects/risks that may occur as a result of declining, including the possibility that treatment may not proceed in the absence of patent IV access • Inform doctor, if clinically indicated • Document advice given in the client's clinical record
Arrangements for referral for medical advice	• Inform and discuss with the doctor in clinic. If not available, discuss with a regional clinical director. • In the event of a medical emergency, e.g. anaphylaxis, provide immediate care in line with UK Resuscitation Council guidance, dial 999 to summon a paramedic response and initiate emergency transfer to NHS care • Document findings/action taken in client's record

3. Description of treatment:	
Name, strength and formulation medicine	Sodium chloride 0.9% solution for injection in 5ml or 10ml ampoules
Legal category	POM
Route / method of administration	Intravenous
Indicate any off-label use (if relevant)	Not applicable
Dose and frequency of administration	• 10mls as a single dose for flushing Either two 5ml ampoules OR one whole 10ml ampoule
Duration of treatment	For the duration of the client's stay at the BPAS clinic and whilst a PIVC remains in situ. Where more than one IV flush is required, each IV flush administration under this PGD constitutes a separate episode. Registered nurses must ensure the PGD criteria are met for each episode.
Total quantity to be administered or quantity to be supplied as TTO	**Administration**: 10mls as a single IV flush **Supply**: Not applicable.
Storage	Stock must be securely stored in accordance with the BPAS Medicines Management policy and in conditions in line with the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Drug interactions	All concurrent medications must be checked for interactions. The following interactions have been identified as clinically significant: • Concomitant administration of other sodium salts may contribute to sodium load. A detailed list of drug interactions is available in the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification and management of adverse reactions	Known side effects with IV use (frequency not known): • Chills • Hypervolaemia • Local Reaction • Paraesthesia • Tremor • Venous thrombosis • Fever • Hypotension • Localised pain • Skin reactions • Vascular irritation This list may not represent all reported side-effects of this medicine. Refer to the most current SmPC for more information. A detailed list of adverse reactions is available in the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org. If necessary, seek appropriate emergency medical advice and assistance.

Management and reporting procedure for adverse reactions	Document any adverse effects in the client's clinical records. If necessary, seek appropriate emergency medical advice and assistance as clinically indicated. Serious adverse drug reactions should be reported to the MHRA via https://yellowcard.mhra.gov.uk/ Adverse drug reactions must also be reported via Datix, including drug name, strength, formulation, batch numbers and expiry dates.
Written information to be given to the individual or carer	• Relevant BPAS client information booklet relevant to their treatment, including Aftercare information • For the administration of medicines, it is good practice to offer the Patient Information Leaflet supplied with the medicine or it can be downloaded from: 44176+44180_49_21_Leaflet_Sodium Chloride-Mefar.indd (medicines.org.uk)
Follow-up advice to be given to the individual or carer	• No specific follow-up required • Inform the individual/carer of possible side effects and their management, including pain/redness at the site of IV cannula insertion • The individual/carer should be advised to seek medical advice in the event of an adverse reaction
Records to be kept	The following must be recorded in the client records in line with the NMC Code and BPAS' Record Keeping policy, using black ink if written: • Patient name, date of birth, any known allergies • Date and time of administration • Indications for use, patient inclusion or exclusion from PGD • Patient history in regard to allergies, previous adverse events and the criteria under which the patient fits the PGD • Details of the medicine including name, strength, dose, route and site of administration • A statement that administration is under PGD • Batch number and expiry date • Signature, printed name and designation of registered health professional administering and detail of double checking, if required • Relevant information provided to the patient/carer • **All records should be clear, legible and contemporaneous.**

4. References and other source material:

- BNF, 2022. Sodium Chloride. Available from: Sodium chloride | Drugs | BNF | NICE
- Electronic Medicines Compendium, 2020. Summary of Products Characteristics: Sodium Chloride Injection BP 0.9% w/v. Available from: Sodium Chloride Injection BP 0.9% w/v - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)
- National Infusion and Vascular Access Society, 2023. Intravenous Administration of Medicines to Adults: Guidance on "line flushing" – version 5. Available from: NIVAS-flushing-guidelines-V5-June-2023.pdf
- NICE, 2017. Medicines practice guideline Patient Group Directions www.nice.org.uk/guidance/mpg2
- Royal College of Nursing, 2016. Standards for infusion therapy. Available from: Standards for Infusion Therapy | Royal College of Nursing (rcn.org.uk)
- UK Resuscitation Council, 2021. Adult basic life support Guidelines | Resuscitation Council UK

5. Audit and ongoing monitoring of this PGD

Please refer to the 'Audit' section of the BPAS Patient Group Direction policy for additional guidance in relation to PGD audit.

The PGD audit tool is available here: British Pregnancy Advisory Service - Audit Tools - All Documents (sharepoint.com).

Units must retain a local copy of the completed audit tool as evidence.

The PGD audit criteria include:

1. Staff member has named, dated and signed the relevant PGD document
2. Client is documented as being referred to a medical practitioner if they are excluded from treatment under the PGD and there is no suitable alternative.
3. Date and time of supply / administration is on the prescription record / CAS2.
4. Client details – name, date of birth, allergies and any previous adverse effects are on the prescription record / CAS2.
5. Details of the medicine – name, strength, dose frequency, quantity, route and site (if by injection) of administration are on the prescription record / CAS2.
6. A statement that supply or administration is by using a PGD is on the prescription record / CAS2.
7. Name and signature (which may be electronic for CAS2 records) of the health professional supplying or administering the medicine is on the prescription record / CAS2.
8. Relevant information was provided to the client or their carer.
9. Client not documented to be allergic to the drug.
10. Paper documentation in related to PGDs are in black ink only.
11. Where appropriate for the medication, correct scheduling has been discussed.
12. Client does not meet any exclusions or contraindications listed in the most up to date PGD.

Appendix A: Approved Practitioner List

Patient Group Direction (PGD) name:	Administration of **Sodium Chloride 0.9% injection as an intravenous flush** for maintaining peripheral intravenous cannula patency and following administration of a bolus injection.	
	Valid from: 16/01/2024	**Expiry:** 31/01/2026

Registered health professional

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove 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. The practitioner MUST sign this document before they can work under this PGD.

I confirm that I have read and understood the contents of this PGD. I confirm that I am willing and competent to work to this PGD within my professional code of conduct.				
Name (print)	**Designation**	**NMC PIN**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation for the above named health care professionals who have signed the PGD to work under it.				
Name	**Position**	**BPAS Treatment Unit**	**Signature**	**Date:**

Note to authorising manager

- Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.
- If registered health professional signatures need to be added at a later date, e.g. due to staffing changes, a separate Approved Practitioner List must be signed, ensuring the correct PGD name and version is detailed.
- This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.
- This list must be stored by the Treatment Unit in a designated folder and be available for immediate inspection, alongside any training / competency records. If a registered professional works across multiple sites, they must sign the Approved Practitioner List for each PGD at each BPAS site where they will use the PGD.