Patient Group Direction For The Administration Of Plasma-Lyte® 148 (pH 7.4) Solution For Infusion By Community Midwives Working Within NHS Grampian

Lead Author:	Consultation Group:	Approver:
Women's and Children's Pharmacist	See relevant page in the PGD	Medicines Guidelines and Policies Group **Authorisation:** NHS Grampian

Signature:		Signature:
		

NHSG Identifier:	Review Date:	Date Approved:
NHSG/PGD/ PlasmaLyte/MGPG1245	April 2024 **Expiry Date:** April 2025	April 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 Board. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD.	
Date of change	**Summary of Changes**	**Section heading**
February 2022	New PGD.	

NHGS Identifier: NHSG/PGD/PlasmaLyte/MGPG1245
Keyword(s): PGD Patient Group Direction Community Midwives PlasmaLyte 148

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:	February 2022
	Completed:	April 2022
	Approved:	April 2022 (Published July 2022)
	Amended and 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 Subhayu Bandyopadhyay **Title:** Clinical Lead, Obstetrics **Contact email:** subhayu.bandyopadhyay@nhs.scot **Signature:** ..... **Date:** 05/07/2022
Senior representative of the professional group who will provide care under the direction	**Name:** Linda Stewart **Title:** Interim Community Midwifery Manager **Contact email:** linda.stewart2@nhs.scot **Signature:** L Stewart **Date:** 24/06/2022
Lead author	**Name:** Ruth Innes **Title :** Women's and Children's Pharmacist **Contact email:** ruth.innes4@nhs.scot **Signature:** ..... **Date:** 21/06/2022
Pharmacist	**Name:** Charlotte Morrison **Title :** Highly Specialised Pharmacist **Contact email:** charlotte.morrison@nhs.scot **Signature:** C Morrison **Date:** 29/06/2022

Approved and authorised for use within NHSG by;

Medicines Guidelines and Policies Group Chair	Signature	Date Signed
Lesley Coyle		21/06/2022

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:
Ruth Innes	**Lead Author:** Women's and Children's Pharmacist
Charlotte Morrison	**Pharmacist:** Highly Specialised Pharmacist
Dr Subhayu Bandyopadhyay	**Medical Practitioner:** Clinical Lead Obstetrics
Linda Stewart	**Senior Representative:** Interim Community Midwifery Manager
Lorraine Johnston	North Aberdeenshire Community Midwifery Team Leader
Megan Blande	Aberdeen City Community Midwifery Team Leader
Judith Falconer	Central Aberdeenshire Midwifery Team Leader
Gillian Valentine	Clinical Midwifery Manager for Maternity Services in Moray
Therese Hendry	South Aberdeenshire Community Midwifery Team Leader

Patient Group Direction For The Administration Of Plasma-Lyte® 148 (pH 7.4) Solution For Infusion By Community Midwives Working Within NHS Grampian

Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise community midwives to administer Plasma-Lyte® 148 to women who have experienced a sudden drop in systolic blood pressure or for the treatment of postpartum haemorrhage. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF) and the individual Summary of Product Characteristics (SmPC). Please note: The contents of this PGD have been based on the information for Plasma-Lyte® 148 (PGD) as contained in the Scottish National Midwifery Formulary (nhsggc.org.uk)
Inclusion criteria	Women requiring resuscitation with intravenous fluids including hypotension and haemorrhage. 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 NHSG consent policy.

Exclusion criteria	• Woman with a known or suspected hypersensitivity to the product or any of its ingredients.
	• Women who have previously experienced an adverse reaction to the medicine.
	• Woman with any of the following:
	  ○ Extracellular hyperhydration or hypervolaemia
	  ○ Severe renal insufficiency (with oliguria/anuria)
	  ○ Heart block
	  ○ Hyperkalaemia
	  ○ Hypernatraemia
	  ○ Hyperchloraemia
	  ○ Hypermagnesaemia
	  ○ Hypochlorhydria
	  ○ Metabolic or respiratory alkalosis
	• Where there is no valid consent.

Precautions and special warnings	Use with caution in women at risk from: • Hypermagnesaemia i.e. mild renal impairment, myasthenia gravis, women being treated with magnesium sulphate infusions (for eclampsia or pre-term labour). • Hypocalcaemia. Plasma-Lyte® 148 contains no calcium and an increase in plasma pH due to alkalinizing effect may lower the concentration of ionized calcium.

	• Hyperkalaemia, particularly women with cardiac disease, renal or adrenocortical insufficiency and acute dehydration, or extensive tissue destruction as occurs with severe burns. Use with caution in women at risk of fluid overload or conditions that cause sodium retention and oedema. Solutions containing sodium should be carefully administered to women with hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function, pre-eclampsia, aldosteronism, or other conditions associated with sodium retention. Must not be infused in the same line as blood. The medicine patient information leaflet should be consulted to ensure that the individual has not experienced a previous hypersensitivity reaction to any ingredients or excipients. Potential for interactions with the following; • Corticosteroids • Potassium sparing diuretics • ACE inhibitors, angiotensin –II receptor antagonists • Tacrolimus, ciclosporin • Digoxin • Acidic drugs such as salicylates, barbiturates and lithium • Alkaline drugs such as ephedrine and pseudoephedrine. If there is a drug interaction, consult with a doctor/GP before administration or supply. Document consultation in maternity record. Refer to current BNF for latest information on interactions.
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 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	Plasma-Lyte® 148 (pH 7.4) Solution for Infusion. Each 1000ml contains: Na^+ 140 mmol K^+ 5 mmol Mg^{2+} 1.5 mmol Cl^- 98 mmol (For full details see the Summary of Product Characteristics)
Legal status	Plasma-Lyte® 148 (pH 7.4) Solution for Infusion is a Prescription only medicine (POM).
Dosage/Maximum total dose	**Maternal resuscitation (including sudden drop in systolic blood pressure):** 500mL or 1 litre bag to be infused through a 14/16 gauge cannula as quickly as possible. Maximum of 2 litres in case of haemorrhage (unless no colloid or blood is available and women still haemorrhaging - continue until help arrives). Maximum of 1 litre to be infused in case of sudden drop of systolic blood pressure not related to postpartum haemorrhage. Ideally when given rapidly the solution should be warmed to no more than 37°C.
Frequency of dose/Duration of treatment	See Dosage/Maximum total dose section above.
Maximum or minimum treatment period	See Dosage/Maximum total dose section above.
Route/Method of administration	Intravenous infusion.
Quantity to be administered	500mL up to 2 litres dependant on indication, see Dosage/Maximum total dose section above.
Storage requirements	Store at room temperature. Use immediately after opening. Use only if the solution is clear, without visible particles and if the container is undamaged.

Follow-up (if applicable)	When used for sudden drop in blood pressure or postpartum haemorrhage, urgent obstetric and anaesthetic help is required. Contact emergency ambulance services and arrange transfer to secondary care. Inform Aberdeen Maternity Hospital Labour Ward immediately. Monitor serum urea and electrolytes. If for postpartum haemorrhage full blood count and send blood for group and screen. Position woman flat on one side. Monitor pulse and BP.
Advice (Verbal)	Referral to medical staff is required.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.

Identifying and managing possible adverse reactions	Refer to the product SmPC for full details of known adverse effects.
	
	• Hypersensitivity/infusion reactions:
	  ○ Tachycardia, palpitations
	  ○ Chest pain/discomfort
	  ○ Dyspnoea, increased respiratory rate
	  ○ Flushing, fever
	  ○ Peripheral oedema
	  ○ Urticaria
	  ○ Infusion site reactions: pain, irritation, infection
	• Hypervolaemia
	• Seizures
	• Thrombophlebitis
	• Venous thrombosis.
	
	This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.
	
	BNF:
	BNF 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. Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA Overuse or administration too quickly can lead to water and sodium overload with oedema. Other symptoms due to excess of other ingredients; • Hyperkalaemia - paraesthesia, muscle weakness, paralysis, cardiac arrhythmias, heart block, cardiac arrest, and mental confusion. • ypermagnesaemia - loss of deep tendon reflexes and respiratory depression (both due to neuromuscular blockade), nausea, vomiting, flushing of the skin, thirst, hypotension due to peripheral vasodilatation, drowsiness, confusion, muscle weakness, bradycardia, coma, and cardiac arrest • Excessive administration of chloride salts may cause a loss of bicarbonate with an acidifying effect. • Excessive administration of compounds, such as sodium acetate and sodium gluconate, which are metabolised to form the bicarbonate anion may lead to hypokalaemia and metabolic alkalosis, especially in women with impaired renal function. Symptoms may include mood changes, tiredness, shortness of breath, muscle weakness, and irregular heartbeat. Muscle hypertonicity, twitching, and tetany may develop especially in hypocalcaemic women. Treatment of metabolic alkalosis associated with bicarbonate overdose consists mainly of appropriate correction of fluid and electrolyte balance. In the case of overdose immediate assessment/treatment is essential - refer to medical staff. Management should be in accordance with established treatment guidelines or see BNF overdose section. For further advice contact National Poisons Centre 0344 892 0111.
Facilities and supplies required	The following are to be available at sites where the medicine is to be administered: • Appropriate storage facilities • 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 Midwives as recognised by the Nursing and Midwifery Council (NMC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's 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 to work under this 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 • Have knowledge and familiarity of the following; ○ 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	Community midwives working within NHS Grampian can be authorised to administer the medicine(s) specified in this PGD by their Professional Line Manager/Consultant/Practice GPs. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising 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 for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This 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 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 • Record of any adverse effects (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: • BadgerNet – Digital Maternity Notes • Individual's GP records if appropriate.

Audit	All records of the medicine 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 Plasma-Lyte® 148 (pH 7.4) Solution for Infusion – Date of revision of text December 2018 accessed 11/02/22. British National Formulary https://about.medicinescomplete.com/ accessed 11/02/22. Scottish National Midwifery Formulary, available from: Midwifery Formulary for Mothers (nhsggc.org.uk). Plasma-Lyte® 148 IV Infusion PGD V1 accessed 11/02/22.

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:

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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 he or she is 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 he or she understands and is 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 his or her individual code of professional practice and conduct.
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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**