Northern Devon Healthcare NHS Trust

Title

Monofer Infusion for iron deficiency in adults Standard Operating Procedure

Author Lead Pharmacist Medicine	**Author's job title** Lead Pharmacist Medicine
Directorate Trustwide	**Department** **Team/Specialty** Pharmacy Medicine

Version	Date Issued	Status	Comment / Changes / Approval
0.1	Jul 2017	Draft	Initial version for consultation
0.2	Aug 2017	Draft	Consulted with senior pharmacists/lead nurse IV therapy
0.3	Aug 2017	Draft	Revised version for consultation
0.4	Sept 2017	Final	For DTC review
1.0	Nov 2017	Final	With DTC amendments
1.1	Aug 2019	Final	Moved the max dose statement above the dose table after feedback. DTC to approve
2.0	Sep 2019	Final	Approved by DTC
2.1	Jan 2021	Draft	Updated generic name. Updated infusion times to match Medusa
3.0	May 2021	Final	Agreed at MMG

Main Contact Jennifer Wilson, Lead Pharmacist Medicine Pharmacy North Devon District Hospital Raleigh Park Barnstaple, EX31 4JB	**Tel: Direct Dial** – 01271 311770 **Tel: Internal** – 3770 **Email**: jwilson48@nhs.net
Lead Director Director of Pharmacy	
Document Class Standard Operating Procedure	**Target Audience** All staff
Distribution List Senior Management Ward sisters	**Distribution Method** Trust's internal website
Superseded Documents	

Issue Date	Review Date	Review Cycle
Feb 2021	Jan 2024	Three years

<table>
<tr><td>Consulted with the following stakeholders: (list all)
• Clinical pharmacists
• Pre-op
• Maternity services
• Day treatment
• Haematology nurses/lab
• Lead nurse MAU
• Clinical nurse specialist IV fluid management</td><td>Contact responsible for implementation and monitoring compliance:
Clinical Nurse Specialist Intravascular Fluid Management

Education/ training will be provided by:
Clinical Nurse Specialist Intravascular Fluid Management</td></tr>
<tr><td colspan="2">Approval and Review Process
• DTC</td></tr>
<tr><td colspan="2">Local Archive Reference
G:\PHARMACY\Policies & Procedures\SOP - Monofer\Monofer SOP 3.0.docx
Local Path
Policies & Procedures\SOP - Monofer\Monofer SOP 3.0.docx
Filename
Monofer SOP 3.0</td></tr>
<tr><td>Policy categories for Trust's internal website (Bob)
Pharmacy/ Haematology</td><td>Tags for Trust's internal website (Bob)
Iron infusion, anaemia, monofer</td></tr>
<tr><td colspan="2">Any revision to an NHSLA document requires the agreement of the Senior Governance Manager (Compliance)</td></tr>
</table>

CONTENTS

1. Background

1.1. **Ferric derisomaltose (Monofer)** is the only iron salt recommended for use in the RD&E and NDDH areas; iron dextran and iron sucrose should not be used.

1.2. Monofer is to be given wherever intravenous iron is requested, except in specified renal dialysis patients under the direction of the renal dialysis team

2. Purpose

2.1. The Standard Operating Procedure (SOP) has been written to:

- Identify the procedure for the prescribing and delivery of Monofer (ferric derisomaltose) infusion within a clinical setting.
- Improve personal care for the patient and reduce the risks associated with inappropriate iron replacement therapy

3. Scope

3.1. This Standard Operating Procedure (SOP) relates to the following staff groups who may be involved in the assessment and delivery of Monofer therapy on the wards:

- Registered nurses
- Medical staff
- Pharmacists

4. Location

4.1. This Standard Operating Procedure Monofer infusion for Iron deficiency can be implemented in all clinical areas where competent staff is available to undertake this role.

4.2. Staff undertaking this procedure must be able to demonstrate continued competence with injectable medicines procedures and anaphylaxis management as per the organisations policy on assessing and maintaining competence.

5. Equipment

- Monofer vials 500mg/5ml as needed
- Sodium chloride 0.9% infusion bag 100 to 500ml depending on patient need
- Vascular access device eg peripheral cannula
- Volumetric infusion pump and compatible administration set

6. Indications for the use of Monofer

6.1. Monofer is indicated for the treatment of iron deficiency:

- When oral iron preparations are ineffective or cannot be used
- Where there is a clinical need to deliver iron rapidly

6.2. The diagnosis must be based on laboratory results.

7. Contraindications

- Hypersensitivity to the active substance, to Monofer or any of its excipients
- Known serious hypersensitivity to other parenteral iron products
- Non-iron deficiency anaemia (e.g. haemolytic anaemia)
- Iron overload or disturbances in utilisation of iron (e.g. haemochromatosis, haemosiderosis)
- Decompensated liver disease
- First trimester of pregnancy
- Ongoing bacteraemia

8. Precautions for use

8.1. Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic reactions. The risk is enhanced for patients with:

- Known allergies including drug allergies
- History of severe asthma, eczema or other atopic allergy

- Immune or inflammatory conditions eg rheumatoid arthritis

8.2. Parenteral iron should be used with caution if acute or chronic infection present.

9. Procedure

9.1. Refer to the NDHT Policy on Prescribing, Preparing and Administering Injectable Medicines

9.2. **Dose calculation**

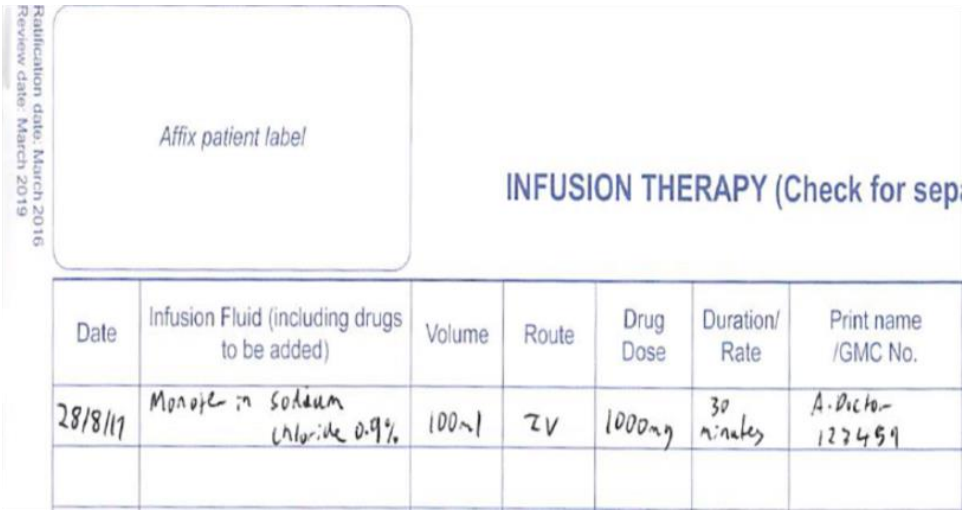
- Determine patients cumulative iron need. For most patients this can be calculated using the simplified table below
- Please note: If the cumulative iron dose exceeds **20 mg iron/kg body weight**, **the dose must be split in two administrations with an interval of at least one week**. It is recommended whenever possible to give 20 mg iron/kg body weight in the first administration. Dependent on clinical judgement the second administration could await follow-up laboratory tests.

Hb (g/L)	Patients with bodyweight 50 kg to 69kg	Patients with body weight 70 kg or greater
100 or greater	1000 mg	1500 mg
less than 100	1500 mg	2000 mg

- In patients who are likely to require individually adjusted dosing such as patients with anorexia nervosa, cachexia, obesity, pregnancy or anaemia due to active bleeding the Ganzoni formula should be used instead – see appendix 1 for the full calculation.

- Please refer to the Management of Iron Deficiency Anaemia in Pregnancy guideline for pregnant women requiring parenteral iron replacement.

Example prescription


Ratification date: March 2016
Review date: March 2019

Affix patient label

INFUSION THERAPY (Check for sep

Date	Infusion Fluid (including drugs to be added)	Volume	Route	Drug Dose	Duration/ Rate	Print name /GMC No.
28/8/19	Monofer in Sodium chloride 0.9%	100ml	IV	1000mg	30 minutes	A. Doctor 123459

9.3. Preparing Monofer infusion

- Monofer should routinely be added to 100ml sterile 0.9% sodium chloride for infusion.
- Volumes greater than 100mls (maximum 500mls) should be based on the individual patient's risk assessment
- The reconstituted solution for injection should be visually inspected prior to use. Use only clear solutions without sediment

9.4. Administering Monofer infusion

- Patient information leaflets are available from Pharmacosmos
- Carry out positive patient identification, gain consent and check for allergies.
- Record baseline early warning score (EWS)
- Doses up to 1000 mg should be administered over more than 15 minutes.
- Doses exceeding 1000 mg should be administered over 30 minutes or more.

10. Monitoring and follow up

10.1. Monofer should only be administered when staff trained to evaluate and manage anaphylactic reactions is immediately available, in an environment where full resuscitation facilities can be assured

10.2. Monitor the patient for signs of a hypersensitivity reaction or intolerance. If detected, stop the infusion immediately and seek medical assistance.

10.3. Report incidents or adverse events via NDHT DATIX system and report to the MHRA via the yellow card scheme.

10.4.

- Patient must remain in the ward or department for at least 30 minutes following completion of infusion
- Prior to discharging day case patients record EWS. Provide advice on actions to take if patient becomes unwell following discharge.
- Some improvement in haemoglobin (Hb) level should be observed after 2 weeks, optimum improvement at 4 weeks. Recheck ferritin level two months following infusion to ensure continued improvement.

11. References

- http://www.injguide.nhs.uk/IVGuideDisplay.asp
- https://www.medicines.org.uk/emc/medicine/23669
- http://ndht.ndevon.swest.nhs.uk/management-of-iron-deficiency-anaemiain-pregnancy-guidelines-v1-2-29oct13/
- Pharmacosmos (2020) Monofer Summary of Product Characteristics
- Rampton, D. et al. (2014) Hypersensitivity reactions to intravenous iron: guidance for risk minimization and management. Haematologica 99(11) 1671-6

12. Associated Documentation

12.1. Northern Devon Healthcare NHS Trust Medicines policy

12.2. MEDUSA online injectable medicines guide

APPENDIX 1

- Ganzoni formula for the calculation of iron needs

$$\underset{[\text{mg iron}]}{\text{Iron need}} = \underset{[\text{kg}]}{\text{Body weight}^{(A)}} \times (\underset{[\text{g/dl}]}{\text{Target Hb}^{(E)}} - \text{Actual Hb})^{(B)} \times 2.4^{(C)} + \underset{[\text{mg iron}]}{\text{Iron for iron stores}^{(D)}}$$

- (A) It is recommended to use the patient's ideal body weight for obese patients or pre-pregnancy weight for pregnant women. Ideal body weight may be calculated in a number of ways e.g. by calculating weight at BMI 25 i.e. ideal body weight = 25 * (height in m)^2
- (B) To convert Hb [mM] to Hb [g/dl] you should multiply Hb [mM] by factor 1.61145
- (C) Factor 2.4 = 0.0034 x 0.07 x 10,000

  0.0034: Iron content of haemoglobin is 0.34%
  0.07: Blood volume 70 ml/kg of body weight ≈ 7% of body weight
  10,000: The conversion factor 1 g/dl = 10,000 mg/l
- (D) For a person with a body weight above 35 kg, the iron stores are 500 mg or above. Iron stores of 500 mg are at the lower limit normal for small women. Some guidelines suggest using 10-15 mg iron /kg body weight.
- (E) Default Hb target is 15 g/dl in the Ganzoni formula. In special cases such as pregnancy consider using a lower haemoglobin target

Worked example:

Patient weight = 60kg

Target Hb = 15g/dL

Actual Hb = 6g/dL

Iron stores = 500mg

Iron dose (mg) = 60kg x (15 – 6) x 2.4 + 500mg = 1796mg

Normally round to nearest 100mg so 1800mg

Remember if the cumulative iron dose exceeds **20 mg iron/kg body weight**, **the dose must be split in two administrations with an interval of at least one week**.
The maximum amount this 60kg patient can have in one dose is 1200mg.

APPENDIX 2

Contraindications:

- Hypersensitivity to the active substance, to Monofer or any of its excipients
- Known serious hypersensitivity to other parenteral iron products
- Non-iron deficiency anaemia (e.g. haemolytic anaemia)
- Iron overload or disturbances in utilisation of iron (e.g. haemochromatosis, haemosiderosis)
- Decompensated liver disease
- First trimester of pregnancy
- Ongoing bacteraemia

Patient requires individualised dosing e.g.

- anorexia nervosa
- cachexia
- obesity
- pregnancy
- anaemia due to bleeding

Y → Refer to Ganzoni formula in appendix 1 or appropriate guideline

N

Calculate Iron requirement using simplified table:

Hb (g/L)	Patients with bodyweight 50 kg to 69kg	Patients with body weight 70 kg or greater
100 or greater	1000 mg	1500 mg
Less than 100	1500 mg	2000 mg

Total iron requirements greater than 20mg/kg of patient body weight

Y → Give first infusion at dose of 20mg/kg, remaining dose may be given after an interval of at least 1 week dependant on clinical judgement of need

N → Give full iron requirement dose

Draw up required dose and add to at least 100ml (maximum 500 ml) sterile 0.9% sodium chloride for infusion

The reconstituted solution for injection should be visually inspected prior to use. Use only clear solutions without sediment

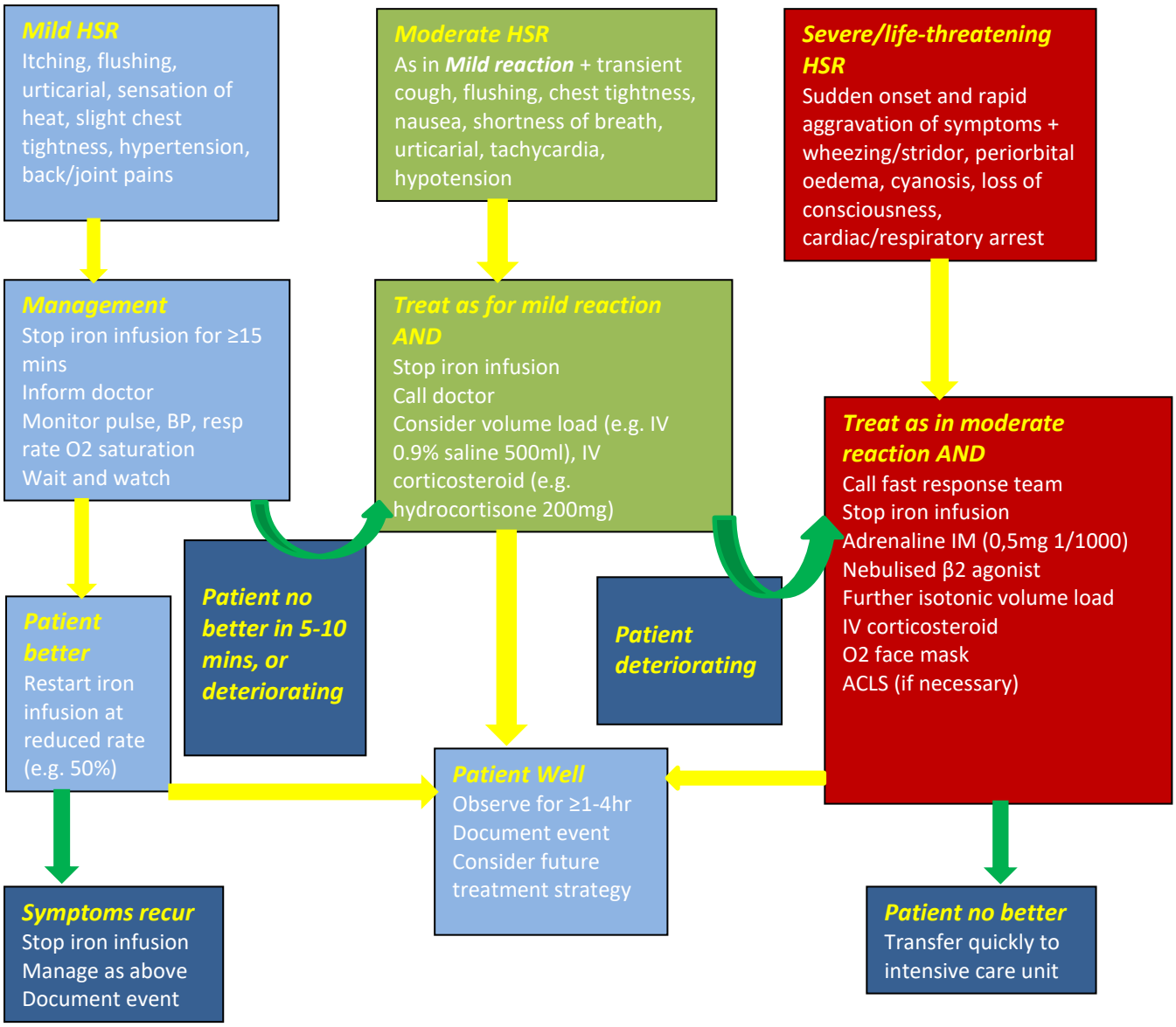
Dose greater than 1000mg

Y → Administer over 30 minutes or more

N → Administer over more than 15 minutes

APPENDIX 3

Grading and management of acute hypersensitivity reactions to intravenous iron infusions



Adapted from: Rampton, D. et al. (2014) Hypersensitivity reactions to intravenous iron: guidance for risk minimization and management. Haematologica 99(11) 1671-6