Document Title:	**FERINJECT IN PREGNANCY AND THE POSTPARTUM PERIOD FOR TREATING IRON DEFICIENCY ANAEMIA**		
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Developed in response to:	National Guidance/Recommendations (i.e. NICE; RCOG) The need to treat anemia in pregnancy and postpartum plus the aim to reduce our blood transfusion rate.		
Contributes to HSC Act 2008 (Regulated Activities) Regulations 2014(Part 3); and CQC Regulations 2009 (Part 4) **CQC Fundamental Standards of Quality and Safety:**			9,11

Issuing Division/Directorate:	Women's & Children's		
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Related Trust Policies (to be read in conjunction with)	(Refer to the main body of the text) 04071 Standard Infection Prevention 04072 Hand Hygiene 06036 Guideline for Maternity Record Keeping including Documentation in Handheld Records 13015 Venofer (iron sucrose) for the Treatment of Iron Deficiency Anaemia in Obstetrics

Document Review History:			
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1.0	Dr S Brayshaw		November 2015
1.1	Dr S Brayshaw	Clarification to Appendix 1	December 2015
1.2	Dr S Brayshaw	Clarification to Appendix 3	8 February 2016
1.3	Dr S Brayshaw	Clarification to Appendix 2, point 1	20 September 2016
1.4	Dr S Brayshaw	Clarification to 6.2 and Appendix 2	4 November 2016
2.0	Dr S Brayshaw	Full Review	24th October 2018
2.1	Louise Middleton	Clarification to point 7.2; Appendix 1 and Appendix 2	23rd August 2019
2.2	Dr S Brayshaw	Clarification to point 7.2 & Appendix 2: points 3 & 8	17th September 2019

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1.0 Purpose

1.1 To guide medical and midwifery staff in the correct indication, dosing and administration of Ferric Carboxymaltose (Ferinject) for the management of iron deficiency anaemia in pregnancy and postpartum.

2.0 Equality and Diversity

2.1 Mid Essex Hospital Services NHS Trust is committed to the provision of a service that is fair, accessible and meets the needs of all individuals.

3.0 Introduction

3.1 Ferinject® is a Ferric Carboxymaltose infusion, which can be used as second line treatment for iron deficiency anaemia when oral iron therapy is deemed inappropriate or has failed (oral iron being the first line treatment). This may be due to malabsorption, poor tolerance, unacceptable side effects or where there is a need to correct iron deficiency and ensuing anaemia urgently.

3.2 Ferinject is an effective treatment option for intrapartum and postpartum anaemia with advantages of a shorter treatment period, better compliance, rapid normalisation of iron storages, and lower incidence of gastrointestinal side effects compared with oral iron therapy.

3.3 The data on Ferinject usage in pregnancy is extremely limited. It is contra-indicated in the 1st trimester of pregnancy. However, Ferinject® is not contraindicated for use in the second and third trimester of pregnancy. Non metabolised Ferric Carboxymaltose is unlikely to pass into the mother's milk and therefore, Ferinject® is not contraindicated in breast-feeding and so suitable for use postnatally.

3.4 Early detection and appropriate management of iron deficiency anaemia may prevent otherwise young and healthy patients from receiving an unnecessary blood transfusion.

4.0 Definition of Iron Deficiency Anaemia

4.1 In the absence of any other diagnosis of anaemia, iron deficiency in pregnancy is defined as:
Hb < 10.5g/dl
MCV < 80 fl
Serum Ferritin < 15µg/l (serum ferritin may be unreliable if raised postpartum)
MCH < 25 pg
Fe < 11µmol/l
Transferrin saturation<15%

5.0 Antenatal and Postnatal Indications and Contra-indications

5.1 Antenatal indications

- Persistant Hb < 100g/l despite 4 weeks of oral iron treatment
- Haemaglobin < 80g/l
- Intolerance or non-compliance with oral iron
- Haemaglobin <105g/L at 34 weeks gestation, so rapid replacement of iron stores required
- Inability to absorb oral iron (e.g. active inflammatory bowel disease)

5.2 Postnatal indications

- If post natal Hb is between 70 g/l and 90 g/l and the patient is asymptomatic and not at significant risk of further haemorrhage, consider Ferinject
- If a post transfusion Hb is between 80 g/l and 90g/l and the patient is asymptomatic, consider Ferinject
- If Hb > 90 g/l the patient is symptomatic, consider Ferinject, rather than transfusion.

5.3 Contraindications:

- Non-iron deficiency anaemia
- Iron overload/haemachromatosis or risk of iron overload e.g. sickle cell disease
- Patients with thalassaemia who are diagnosed with iron deficiency anaemia should be reviewed by a haematologist for appropriate management and treatment**.** Patients with **thalassaemia** or **sickle cell disease** should **NEVER** routinely receive iron therapy either oral or intravenous
- Previous hypersensitivity to parenteral iron
- Severe asthma or eczema or atopy
- Hepatic impairment
- Active infection
- 1st Trimester pregnancy

6.0 Dosage of Ferinject

There is a simplified dosing of Ferinject now available. Please use the woman's booking weight. The table below gives the recommended total dose. This will need to be **administered in more than one dose if the dose is greater than 15mg/kg**. Wait one week before giving the remaining dose.

Hb(g/L)	Body weight 35-<70kg	Body weight >70kg
<100	1500 mg iron	2000 mg iron
100-140	1000 mg iron	1500 mg iron
>140	500 mg iron	500 mg iron

7.0 Observations and Monitoring

7.1 The safety profile for Ferinject is similar to that of Venofer. The most common side effects are headache (3%), gastrointestinal symptoms and rash. Anaphylaxis is very rare making it a safe preparation to use, though it is recommended that hydrocortisone, chlorpheniramine and adrenaline be available in case of a severe reaction.

7.2 The patient should be given MEHT190003 Ferinject information leaflet to read before the infusion.

7.3 Monitoring During Administration**:**

- Full set of observations (pulse, temperature, blood pressure, respiratory rate and saturations) prior to commencing the infusion, and every 5 minutes during the infusion. Observations should be recorded on the MEOWS chart.
- Check the administration site for any injection site reactions.
- During the infusion the patient should have one-to-one midwifery care being alert for the signs and symptoms of anaphylaxis
- The fetal heart should be auscultated as part of the initial observations and should be documented in the health care records
- The woman should have observations recorded every 15 mins after the infusion for 30 minutes
- Print and complete appendices 1, 2 and 3

7.4 Women can go home 1 hour after the end of the infusion if her observations remain normal.

7.5 Following completion of the infusion, the cannula should be flushed to remove any residue of the Ferinject infusion.

8.0 Adverse Effects

8.1 Side effects:

- Metallic taste
- Nausea and vomiting
- Hypotension
- Headache
- Paraesthesia
- Abdominal pain
- Muscular pain
- Fever
- Urticaria
- Flushing
- Oedema
- Phlebitis/venous spasm
- Anaphylaxis/ anaphylactoid reactions (extremely rare)

8.2 Resuscitation equipment should be available in the room with ready access to anaphylaxis drugs before the initial test dose.

8.3 Rapid infusion may lead to hypotension. Stop the infusion and recommence at a lower rate once the blood pressure normalizes.

87.4 Mild allergic reactions:
- Stop infusion
- Full set of maternal observations
- Chlorphenamine if required
- Contact obstetric team regarding restarting the infusion at a slower rate

8.5 Anaphylaxis:
- Stop infusion
- Manage as per usual anaphylaxis

9.0 Follow up of Patients

9.1 **Antenatal patients**
A repeat FBC should be taken 21-28 days after adequate treatment is given. This should show a rise in Hb of 20-30g/l in most women, but a rise in MCV and MCH is indicative that treatment is working and iron is being taken up into the red blood cells. Serum Ferritin should also be taken to indicate the state of the iron stores and whether further treatment is required to replenish these.

9.2 **Postnatal patients**
Follow up FBC need to be arranged with the GP or community midwives for 4 weeks after treatment. Please ask the CMW arrange this.

10.0 Staffing and Training

10.1 Midwives and obstetric doctors will receive information regarding the administration of Ferinject from the Labour Ward Co-ordinators.

10.2 All midwifery and obstetric staff must attend yearly mandatory training which includes skills and drills training.

10.3 All midwifery and obstetric staff are to ensure that their knowledge and skills are up-to-date in order to complete their portfolio for appraisal.

11.0 Professional Midwifery Advocates

11.1 Professional Midwifery Advocates provide a mechanism of support and guidance to women and midwives. Professional Midwifery Advocates are experienced practising midwives who have undertaken further education in order to supervise midwifery services and to advise and support midwives and women in their care choices.

12.0 Infection Prevention

12.1 All staff should follow Trust guidelines on infection prevention by ensuring that they effectively 'decontaminate their hands' before and after each procedure.

12.2 All staff should ensure that they follow Trust guidelines on infection prevention, using Aseptic Non-Touch Technique (ANTT) when carrying out procedures

13.0 Audit and Monitoring

13.1 An audit form will be completed on all women who have Ferinject; in accordance with the Clinical Audit Strategy and Policy and the Maternity annual audit work plan. The Women's and Children's Clinical Audit Group will identify a lead for the audit.

13.2 The findings of the audit will be reported to and approved by the Multi-disciplinary Risk Management Group (MRMG) and an action plan with named leads and timescales will be developed to address any identified deficiencies. Performance against the action plan will be monitored by this group at subsequent meetings.

13.3 The audit report will be reported to the monthly Directorate Governance Meeting (DGM) and significant concerns relating to compliance will be entered on the local Risk Assurance Framework.

13.4 Key findings and learning points from the audit will be submitted to the Clinical Governance Group within the integrated learning report.

13.5 Key findings and learning points will be disseminated to relevant staff.

14.0 Guideline Management

14.1 As an integral part of the knowledge, skills framework, staff are appraised annually to ensure competency in computer skills and the ability to access the current approved guidelines via the Trust's intranet site.

14.2 Quarterly memos are sent to line managers to disseminate to their staff the most currently approved guidelines available via the intranet and clinical guideline folders, located in each designated clinical area.

14.3 Guideline monitors have been nominated to each clinical area to ensure a system whereby obsolete guidelines are archived and newly approved guidelines are now downloaded from the intranet and filed appropriately in the guideline folders. 'Spot checks' are performed on all clinical guidelines quarterly.

15.0 Communication

15.1 A quarterly 'maternity newsletter' is issued and available to all staff including an update on the latest 'guidelines' information such as a list of newly approved guidelines for staff to acknowledge and familiarise themselves with and practice accordingly.

15.2 Approved guidelines are published monthly in the Trust's Focus Magazine that is sent via email to all staff.

15.3 Approved guidelines will be disseminated to appropriate staff quarterly via email.

15.4 Regular memos are posted on the guideline notice boards in each clinical area to notify staff of the latest revised guidelines and how to access guidelines via the intranet or clinical guideline folders.

16.0 References

Ferinject Monograph (http://www.ferinject.co.uk/pdf/Monograph.pdf)

UK guidelines on the management of iron deficiency in pregnancy, British Committee for Standards in Haematology

Appendix 1

To be referred to by doctors prior to infusion of Ferinject

Investigations to be undertaken:

- Full blood count
- Ferritin
- CRP
- Liver function tests

Exclude contraindications (please tick each point to confirm it is excluded):

- Non iron deficiency anaemia
- Risk of iron overload e.g. with haemaglobinopathies such as Sickel cell or thalassaemia.
- Allergy to intravenous iron
- Severe asthma, ezcema or atopy.
- First trimester of pregnancy
- Hepatic impairment
- Active infection

Confirm Ferinject is indicated:

The patient must be anaemic with a serum ferritin <30 µg/l

Antenatal women (2^{nd} and 3^{rd} trimester only):

- Persistent Hb <100g/L despite 4 weeks of oral iron, or
- Hb <80g/L, or
- Hb<105 g/L at 34/40, or
- Inability to absorb oral iron

Postnatal women:

- Haemoglobin between 70 and 100 g/L without symptoms such as hypotension and tachycardia and not at significant risk of further haemorrhage, or
- Post transfusion Hb 80-90 g/L

Calculate the dose:

Hb(g/L)	Body weight 35-<70kg	Body weight >70kg
<100	1500 mg iron	2000 mg iron
100-140	1000 mg iron	1500 mg iron
>140	500 mg iron	500 mg iron

DO NOT ADMINISTER MORE THAN 15MG/KG IN ONE GO (MAX 1000MG IN A SINGLE DOSE). The woman may need two doses to be given a week apart. See maximum single dose chart below.

- Prescribe on the drug chart. Write clear instructions to dilute the Ferinject doses up to and including 500mg into 100mls of Sodium Chloride 0.9% and infuse over 15 mins. Doses greater

than 500mg of Ferinject dilute into 250mls of Sodium Chloride 0.9% and administer over 30 minutes.

Appendix 2

Instructions for Midwives Administering Ferinject

1. Check the doctor has filled in the Ferinject patient information chart. Record results for FBC, LFT, Ferritin and CRP.

2. Ensure the woman has a bed on Labour Ward

3. The patient should be given MEHT190003 Ferinject information leaflet to read before the infusion.

4. Check the drug chart has been completed and the maximum single dose not exceeded

Booking weight	Maximum single dose of Ferinject
40-46kg	600mg
47-53kg	700mg
54-59kg	800mg
60-66kg	900mg
>66kg	1000mg

5. Insert cannula take blood pressure, pulse respiratory rate and saturations.

6. Complete a MEOWS chart

7. Listen to the fetal heart in antenatal women.

8. Stay with the woman during the infusion; record her observations every 5 minutes.
   If the woman experiences any pain during the infusion; stop immediately. Assume the cannula has tissued and re-site the cannula.

9. Once the infusion has finished record 3 more set of observations every 15 minutes.

10. Flush the cannula when the infusion has finished.

11. Warn the woman she may have a metallic taste, may feel a bit nauseous, and may get a headache. Warn her that a severe allergic reaction is possible but very rare.

12. Give her a form for a repeat full blood count and ferritin levels to be done at 3-4 weeks after the infusion if she is antenatal.

13. If the woman is postnatal arrange for her community midwife to check her full blood count in 4 weeks.

14. Complete an audit form (appendix 3) and put in the box in the Labour Ward Office.

Appendix 3

Audit Form for Women Receiving Ferinject

Date:

Name:

DOB:

Hospital number:

Starting Hb:

Antenatal or postnatal:

If antenatal: number of weeks gestation:

Dose of Ferinject received:

Any further doses planned (Y/N):

The woman must be given a form for a repeat FBC and ferritin levels check at 3-4 weeks post Ferinject. Tick here to confirm this has been done:

Any adverse effects (please describe):

PLACE IN BOX IN LABOUR WARD OFFICE WHEN COMPLETE
THANK YOU