# MANAGEMENT OF ANAEMIA IN PREGNANCY
Including Total Dose Iron Infusion (Ferinject)

<table>
<thead>
<tr>
<th>Version:</th>
<th>3.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratified by:</td>
<td>Maternity Quality Board</td>
</tr>
<tr>
<td>Date ratified:</td>
<td>16/06/2016</td>
</tr>
<tr>
<td>Approving Committee/Group (Date)</td>
<td>Medicines Management Committee (22/09/2016)</td>
</tr>
<tr>
<td>(NB: All Procedural Documents which include details of drugs or their management must be approved by the Medicines Management Committee)</td>
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</table>
| Name and Title of originator/author: | Bini Ajay Consultant Obstetrician  
Karen Rooke (Supervisor of Midwives) |
| Date issued: | September 2016 |
| Review due date: | September 2019 |
| Target audience: | Midwives, Obstetricians and Maternity staff |
| Related CQC Domain (Please tick) | ☑ Safe  ☑ Effective  ☑ Caring  
☐ Responsive  ☐ Well-Led |
| Superseded documents | Management of Anaemia in Pregnancy Version 2.0 |
| Relevant Standards(e.g. HSE, Health and Social Care Act) | |
| Acknowledgements | None |
| Key Words | Anaemia, pregnancy, iron infusion |
EXECUTIVE SUMMARY

Iron deficiency is the most common cause of anaemia during pregnancy and is associated with low birth weight in the newborn and preterm delivery, as well as increased risk of maternal morbidity and need for blood transfusion following delivery. Women should be offered screening for anaemia and appropriate management of anaemia. If iron deficiency is identified then oral iron should be the first line treatment. Parenteral iron infusion should be considered if oral treatment is unsuccessful or the woman is nearing term and haemoglobin is less than 100g/L. This guideline contains the procedure to follow when administering the parenteral iron infusion Ferinject®.
1 INTRODUCTION

The most common cause of anaemia in pregnancy is iron deficiency. This is as a result of increasing maternal iron requirements and an increase in red cell mass. In normal pregnancy maternal plasma volume increases by up to 50% and the red cell mass gradually increases by about 20%. Hence, the haemoglobin (Hb) concentration drops.

Iron deficiency anaemia is a risk factor for preterm delivery and low birth weight in the newborn.

2 PURPOSE

To ensure pregnant women are offered screening for anaemia in line with national screening guidance.

To ensure anaemia is managed when identified and in advance of delivery.

3 DEFINITIONS

In the UK, accepted pregnancy haemoglobin (Hb) levels should not fall below;

<table>
<thead>
<tr>
<th>Gestation</th>
<th>Hb (g/L)</th>
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<tr>
<td>Up to 12 weeks</td>
<td>110</td>
</tr>
<tr>
<td>28-30 weeks</td>
<td>105</td>
</tr>
</tbody>
</table>

There are no strict criteria for mild, moderate or severe anaemia. Reference can be taken from WHO-1989;

<table>
<thead>
<tr>
<th>Type</th>
<th>Hb (g/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild anaemia</td>
<td>100-109</td>
</tr>
<tr>
<td>Moderate</td>
<td>70-99</td>
</tr>
<tr>
<td>Severe</td>
<td>&lt;70</td>
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</table>

Other causes of anaemia include folate deficiency, vitamin B12 deficiency, bone marrow suppression, sickle cell disease, chronic blood loss and underlying malignancies. In the event of diagnosis of folate deficiency or vitamin B12 deficiency shared care of the woman between a Consultant Obstetrician and Haematologist is recommended.

4 ACCOUNTABILITIES AND RESPONSIBILITIES

Chief Executive
Has ultimate responsibility for the implementation and monitoring of the policies in use in the Trust.

Clinical Leads/Head of Midwifery
Where Clinical Leads/Head of Midwifery are asked to ratify this guideline they are responsible for the review of the guideline and the final ratification prior to the guideline being implemented. This ratification process will take place following the consultation and approval process.

Practice Review and guideline group

June 2016
The group are responsible for the consultation and approval process required during the development of guidelines for the Maternity Unit.

**The Maternity Quality Board**
The Maternity Quality Board is responsible for the ratification of guideline prior to implementation. This ratification process will take place following the consultation and approval process.

**All Staff**
It is incumbent on relevant staff when asked, to provide comments and feedback on the content and practicality of the guideline. It is the duty of all staff when asked, to provide assistance during the development and review stages of guideline formulation.

It is the responsibility of the midwife at booking and the 28 week appointment to offer screening for anaemia, to follow up the results and make the appropriate referrals as necessary.

## 5 PROCEDURE

### 5.1 Diagnosis and referral

Pregnant women are offered screening for anaemia and haemoglobinopathies at their booking appointment and again at 28 weeks gestation.

If the Haemoglobin level is less than 105 g/L in the antenatal period, consider iron deficiency once haemoglobinopathies have been excluded.

Women with Hb of less than 100 g/L should be referred as early as possible to an Obstetric consultant clinic to make a clear management plan for pregnancy and delivery.

Estimation of the haemoglobin level is used as the first indicator of anaemia. However, because of the diverse pathogenesis of anaemia (e.g., iron deficiency anaemia, thalassaemia, sickle cell anaemia) the use of haemoglobin as the sole means of diagnosing anaemia is not recommended, thus more sensitive and specific tests should be undertaken. Serum ferritin is the most sensitive single screening test to detect adequate iron stores. Using a cut-off of 30 micrograms/litre sensitivity of 90% has been reported.

Women who refuse blood products should always be managed in line with the Trust Refusal of blood components and blood products guideline.

Jehovah witness women with anaemia should be referred to a consultant as early as possible and should have a discussion about cell saver in case of Caesarean section.

In women with anaemia who refuse blood transfusion and Hb <100g/L when planning Cesarean section (CS):
- cell saver should be considered
- inform anesthetist

### 5.2 Management

Oral iron is the preferred first line treatment for iron deficiency. 100-200 mg of elemental iron daily is recommended. Higher doses are not beneficial. There are 3 types of iron supplements:
Ferrous Sulphate, Ferrous Gluconate and Ferrous Fumarate. 200mg of ferrous sulphate provides 65 mg of elemental iron.

To minimize side effects of oral iron, commence with half the recommended dose, gradually increasing to the full dose. Ascorbic acid enhances absorption, women should either be prescribed vitamin C supplement or advised to take iron tablet with orange juice about one hour after food. Oral iron can cause gastrointestinal side effects resulting in poor compliance.

The threshold for commencing oral iron supplements should be lower in cases of multiple pregnancies.

Women must be given dietary advice. Heme Iron, found in animal sources, is highly available for absorption. Non-heme iron on the other hand, found in vegetable sources, is less available. Iron rich foods include lean red meat, fish, poultry, dried fruits, whole-grain breads and iron fortified cereals.

Failure to respond to iron therapy should prompt further investigation and may suggest an incorrect diagnosis, co-existing disease, malabsorption, non-compliance or blood loss.

5.2.1 Parenteral iron

Ferinject® (ferric carboxymaltose) is an intravenous (IV) iron preparation that is indicated for the treatment of iron deficiency when oral preparations are ineffective or cannot be used. The diagnosis must be based on laboratory tests.

It has proven clinical efficacy in a number of diseases characterised by iron deficiency (ID) and a well-established safety profile.

Please see Ferinject Flowchart Appendix C

5.2.2 Indications for use

1. Persistent iron deficiency anaemia due to oral iron intolerance e.g. inflammatory bowel disease (Hb < 100g/L, 2nd or 3rd trimester)

2. Demonstrated patient non-compliance to oral iron therapy

3. Treatment failure on oral iron after four week trial (expected rise of Hb concentration of <10-20g/L)

4. Blood transfusion declined e.g. Jehovah’s Witness.

5. Anaemia near term (36 weeks gestation or more, Hb < 100g/L)

6. Need rapid replacement of iron stores due to severe/worsening anaemia: Hb <90g/L with uncontrolled menorrhagia

5.2.3 Contraindications to Ferinject

1. Anaemia not attributable to iron deficiency

2. Iron overload or disturbances in utilisation of iron.

3. Known hypersensitivity to any iron preparation
4. Clinical or biochemical evidence of liver damage

5. Acute/ chronic infection

6. First trimester of pregnancy

5.2.4 Side effects

Common (≥1/100 to <1/10 patients)
- Headaches/dizziness
- Hypertension
- Nausea
- Injection site reactions

Uncommon (≥1/1000 to <1/100 patients)
- Hypersensitivity
- Paraesthesia/Dysgeusia
- Tachycardia
- Hypotension
- Dysnoea
- Vomiting, dyspepsia, abdominal pain, constipation, diarrhoea
- Pruritis, urticaria, erythema
- Myalgia, back pain, muscle spasms
- Pyrexia, fatigue, peripheral oedema, chest pain

Rare (≥1/10000 to <1/1000 patients)
- Anaphylactoid reactions
- Loss of consciousness
- Anxiety
- Phlebitis
- Bronchospasm
- Flatulence
- Angioedema
- Rigors/malaise

5.2.5 Special Warnings and precautions

- Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic/anaphylactoid reactions. Hypersensitivity reactions have also been reported after previously uneventful doses of parenteral iron complexes.
- The risk is enhanced for patients with known allergies including drug allergies, including patients with a history of severe asthma, eczema or other atopic allergy.
- There is also an increased risk of hypersensitivity reactions to parenteral iron complexes in patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis).
- Ferinject® should only be administered when staff trained to evaluate and manage anaphylactic reactions are immediately available, in an environment where full resuscitation facilities can be assured. Each patient should be observed for adverse effects for at least 30 minutes following each Ferinject® injection. If hypersensitivity
reactions or signs of intolerance occur during administration, the treatment must be stopped immediately.

- Facilities for cardio respiratory resuscitation and equipment for handling acute anaphylactic/anaphylactoid reactions should be available, including an injectable 1:1000 adrenaline solution. Additional treatment with antihistamines and/or corticosteroids should be given as per trust resuscitation policy.
- In patients with liver dysfunction, parenteral iron should only be administered after careful benefit/risk assessment.
- Parenteral iron must be used with caution in case of acute or chronic infection, asthma, eczema or atopic allergies.
- It is recommended that the treatment with Ferinject® is stopped in patients with ongoing bacteraemia. Therefore, in patients with chronic infection a benefit/risk evaluation has to be performed, taking into account the suppression of erythropoiesis.
- Caution should be exercised to avoid paravenous leakage when administering Ferinject®. Paravenous leakage of Ferinject® at the injection site may lead to irritation of the skin and potentially long lasting brown discoloration at the site of injection. In case of paravenous leakage, the administration of Ferinject® must be stopped immediately.
- One mL of undiluted Ferinject® contains up to 5.5 mg (0.24 mmol) of sodium. This has to be taken into account in patients on a sodium-controlled diet.
- The use of Ferinject® has not been studied in children under the age of 14 years old.
- Do not administer 20 mL (1,000 mg of iron) as an infusion more than once a week.

5.3 Patient information and consent

Prior to administration of Ferinject, the woman must be given all relevant information in relation to the drug and verbal informed consent obtained.

5.4 Management of administration

5.4.1 Dose

- A single dose of Ferinject® must not exceed 20mg/kg (body weight) or 1000mg, whichever is less.
- If further iron carboxymaltose (Ferinject®) is required to reach the level of iron needed, wait for at least 1 week before giving the remaining dose
- Example 1: 40kg patient: dose of Ferinject® = 40x20 = 800mg single dose
- Example 2: 70kg patient: dose of Ferinject® = 70x20 = 1000mg initial dose + review in clinic to evaluate need for further 400mg dose

All women weighing >50kg should be prescribed a single dose of 1000mg.

Women ≥36 weeks gestation should be reviewed 2 weeks following infusion to assess need for a second infusion. Women <36 weeks gestation should be reviewed in 4 weeks when Ferinject has reached it’s peak action.
5.4.2 Maternal Observations

- BP and pulse should be performed prior to the infusion, following the infusion (15mins) and after a further 15 mins.
- Flush the cannula with normal saline prior to removal.
- Observe the patient for 30 minutes following the infusion.
- Fetal monitoring is not required during the infusion as long as the patient is feeling enough fetal movements.
- Women can go home 30 minutes after the infusion if all observations are stable.

5.4.3 Location of administration

Ferinject can be administered on Day Assessment Unit (DAU) or Antenatal ward as long as there are staff available for appropriate monitoring (as above). There is no need for overnight stay on the ward.

5.4.4 Dilution and Intravenous infusion administration

Ferinject may be administered by intravenous infusion, in which case it must be diluted. The maximum single dose is 20 mg iron/kg body weight, but should not exceed 1,000 mg iron.

For infusion, Ferinject must only be diluted in sterile 0.9% m/V sodium chloride solution as shown in Table 1. Note: for stability reasons, Ferinject should not be diluted to concentrations less than 2 mg iron/mL (not including the volume of the ferric carboxymaltose solution).

Table 1: Dilution plan of Ferinject for intravenous infusion

<table>
<thead>
<tr>
<th>Volume of Ferinject required</th>
<th>Equivalent iron dose</th>
<th>Maximum amount of sterile 0.9% m/V sodium chloride solution</th>
<th>Minimum administration time</th>
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</thead>
<tbody>
<tr>
<td>2 to 4 mL</td>
<td>100 to 200 mg</td>
<td>50 mL</td>
<td>-</td>
</tr>
<tr>
<td>&gt;4 to 10 mL</td>
<td>&gt;200 to 500 mg</td>
<td>100 mL</td>
<td>6 minutes</td>
</tr>
<tr>
<td>&gt;10 to 20 mL</td>
<td>&gt;500 to 1,000 mg</td>
<td>250 mL</td>
<td>15 minutes</td>
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</table>

5.5 Management of adverse side effects

Facilities for cardio-pulmonary resuscitation must be available.

Patients with low iron binding capacity and/folic acid deficiency are particularly at risk of an allergic or anaphylactoid reaction.

5.5.1 Mild allergic reactions

1. Stop infusion
2. Record temperature, pulse, blood pressure, respirations, O2 saturations.
3. Chlorphenamine 10mg iv slowly can be given as prescribed by the doctor if mild reactions such as itching do not abate.
4. Recomence infusion at a slower rate and observe the woman closely.

5.5.2 Severe anaphylactic reaction

1. Stop infusion
2. Call 2222 for medical emergency
3. IM adrenaline should be administered immediately and after supportive cardio-pulmonary resuscitation procedures initiated.

5.6 Follow up

A plan must be in place before the woman goes home. If the woman is over 36 weeks pregnant a 2 week follow up appointment must be given. For women under 36 weeks pregnant a 4 week follow up appointment is given. Haemoglobin and ferritin levels should be checked for the follow up appointment.

Oral iron can be prescribed if needed and should be started at least 5 days after the last infusion.

5.7 Blood transfusion

There are no firm criteria for initiating red cell transfusion.

The decision to give a blood transfusion should be made on both a clinical and haematological basis.

Transfusion is rarely indicated in a stable woman when the Hb is greater than 100 g/L and is almost always indicated when less than 60g/L.

Please refer to the Trust Blood Transfusion Policy for further guidance.

5.7.1 Intrapartum anaemia

If the Hb is less than 70 g/L in labour or in the immediate postpartum period, the decision to transfuse should be made according to the individual’s medical history, age and symptoms.

5.7.2 Postpartum anaemia

If the Hb is less than 70-80 g/L in postnatal period, where there is no continuing or threat of bleeding, the decision to transfuse should be made on an informed individual basis. In fit, healthy, asymptomatic patients there is little evidence of the benefit of blood transfusion.

Ferinject can also be given for treatment of post-partum anaemia.

6 TRAINING

Staff administering Ferinject infusion must be trained in the administration of intravenous infusions. They must be aware of the management of infusion of Ferinject. Basic Life Support
skills and anaphylaxis skills are required in the event of an adverse reaction and all obstetric and midwifery staff must be up to date with this mandatory training.

6.1 Equality Impact Assessment

The Equality Impact Assessment for this policy is attached in Appendix A.
## 7 MONITORING COMPLIANCE

<table>
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<th>Element to be monitored</th>
<th>Lead</th>
<th>Tool</th>
<th>Frequency</th>
<th>Reporting arrangements</th>
<th>Action Lead(s)</th>
<th>Change in practice and lessons</th>
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<td>Dietary advice offered when anaemia identified</td>
<td>Obstetric SpR</td>
<td>Audit tool</td>
<td>An audit of the key elements to be monitored will be carried out and once compliance achieved will be repeated three yearly</td>
<td>Clinical Governance meeting</td>
<td>Clinical Midwifery Managers Clinical Leads</td>
<td>Changes to practice will be discussed at the Clinical Governance meeting and implemented via the Quality Board</td>
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<td>Audit tool</td>
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<td>Clinical Midwifery Managers Clinical Leads</td>
<td>Changes to practice will be discussed at the Clinical Governance meeting and implemented via the Quality Board</td>
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<td>Parental iron prescribed when indicated</td>
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<td>Clinical Governance meeting</td>
<td>Clinical Midwifery Managers Clinical Leads</td>
<td>Changes to practice will be discussed at the Clinical Governance meeting and implemented via the Quality Board</td>
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<tr>
<td>Procedure to be followed for Total dose iron infusion</td>
<td>Obstetric SpR</td>
<td>Audit tool</td>
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<td>Clinical Governance meeting</td>
<td>Clinical Midwifery Managers Clinical Leads</td>
<td>Changes to practice will be discussed at the Clinical Governance meeting and implemented via the Quality Board</td>
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<tr>
<td>Number of staff attending basic life support training</td>
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<td>TNA Database</td>
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<td>Clinical Midwifery Managers Clinical Director</td>
<td>Findings reported to the Risk Management meeting. Clinical midwifery managers and the Clinical Director follow up staff who do not attend training</td>
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</tbody>
</table>
8 REFERENCES

Ferinject® Summary of Product Characteristics 2015


9 ASSOCIATED DOCUMENTATION

Croydon Health Services NHS Trust- Maternity Guideline: Obstetric haemorrhage
Croydon Health Services NHS Trust- Maternity Guideline: Women who refuse Blood Transfusion and Blood Products
Croydon Health Services NHS Trust- Blood Transfusion Policy

10 VERSION HISTORY TABLE

<table>
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<th>Version</th>
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<th>Author</th>
<th>Ratified by</th>
<th>Comment/Reason for change</th>
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<td>1.0</td>
<td>September 2010</td>
<td>Latika Narang SpR Obstetrics</td>
<td>Maternity Quality Board</td>
<td>New Guideline</td>
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<td>2.0</td>
<td>March 2015</td>
<td>Bini Ajay Becci Tether</td>
<td>Maternity Quality Board</td>
<td>Full guideline review and reformatting</td>
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<td>3.0</td>
<td>May 2016</td>
<td>Bini Ajay</td>
<td>Maternity Quality Board</td>
<td>Inclusion of Ferinject. Removal of Cosmofer</td>
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APPENDIX A – EQUALITY IMPACT ASSESSMENT

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

<table>
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<th>Protected Characteristic</th>
<th>Positive Impact</th>
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<th>Reasons for decision</th>
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Policy: Anaemia in Pregnancy Version 3.0 | Date: 16/06/2016
Officer conducting this Analysis: Karen Rooke

APPENDIX B – CONSULTATION TEMPLATE

2. Procedural Document Author: Bini Ajay
3. Group/Committee Consulted | Date
   - Practice review and guidelines meeting
   - MMC | Feb 2016/ June 2016
   - Quality Board | June 2016
4. Name and Title of Key Individuals Consulted | Date
5. Comments received:
   - Removal of use of Cosmofer for iron infusions
   - Ferinject guidance for use included
   - MMC | Feb 2016

June 2016
- Page 4 – paragraph 3
  o Consider placing the individual statements in separate sentences to make it clearer to read.
- Page 6 – Section 3.2.5
  o Section midway through page containing contra-indications to Iron does not make sense. Please look into these and remove or reword.
- Page 7 – Section 3.4.3
  o Please write the full term for “FAU.”
- Page 8 – Section 3.4.4
  o Paragraph 2 – the table is referenced as “Table 3” instead of “Table 1.”
- Page 9 – Training
  o The Iron is referenced as “Cosmofer,” which is another brand of Iron that is not being used. Please change this to “Ferinject,” and review the rest of the guideline for any other mistaken entries of Cosmofer. Accountabilities and Responsibilities section are not included.

**MMC June 2016**

Page 4 – change HB<10 to 100g/L
- Remove cross match 2 units
Page 4- 3.2 Remove sentence ‘Slow release polysaccharide preparations improve absorption and improve compliance.
Page 5 3.2.3 (3) change to any iron preparation
Page 6 3.2.5 point 5- Chage ‘as appropriate’ to as per trust resusitation policy.
Page 8 3.5.1 (3) correct spelling – Chlorphenamine
Page 8 3.5.2 (2) change ‘crash call’ to Call 2222
Page 8 3.7 change 10g/dl to 100g/L and 6g/dl to 60g/L

**MMC Chair’s Action August 2016**

- Please use the updated policy template, which includes sections:
  - executive summary
  - accountabilities and responsibilities
- Page 4 - section 3.2 management, paragraph 1 – spelling of ferrous fumarate.
- Page 7 - paragraph before 3.4.2 - review suggested 2 week follow-up appointment after initial Ferinject dose as its peak action occurs around 4 weeks.
- Page 8 - Paragraph 3 under 3.6 - include space in "lastinfusion".
- Page 8 –section 3.7 blood transfusion – please refer to trust blood transfusion guidelines.
- Page 14 - box in second column on third row - remove "e.g."

**Quality Board June 2016**

‘Hope’ ward changed to antenatal ward
APPENDIX C – USE OF FERINJECT FLOWCHART

Patient with iron deficiency anaemia (IDA)

No contraindications to oral iron therapy (intolerance, malabsorption, IBD etc.)

AND

No clear indication for parenteral iron therapy (eg Ferinject® – see Appendix 1 below)

Any indication for parenteral iron therapy (see Appendix 1 below)

AND

No contraindication to parenteral iron therapy (see Appendix 2 below)

Any indication for parenteral iron therapy (see Appendix 1 below)

AND

Contraindication to parenteral iron therapy (see Appendix 2 below)

Oral iron therapy (eg ferrous sulphate)

Parenteral iron therapy (Ferinject®)

Review after four week trial

Failure of four week trial

Appendix 1: INDICATIONS FOR FERINJECT *

1. Persistent iron deficiency anaemia due to oral iron intolerance e.g. inflammatory bowel disease (Hb < 100g/L, 2nd or 3rd trimester)
2. Demonstrated patient non-compliance to oral iron therapy
3. Treatment failure or oral iron after four week trial (rise of Hb concentration of <10-20g/L)
4. Blood transfusion declined e.g. Jehovah’s Witness.
5. Anaemia near term (36 weeks gestation or more, Hb < 100g/L)
6. Need rapid replacement of iron stores due to severe/worsening anaemia: Hb <90g/L with uncontrolled menorrhagia

Appendix 2: CONTRAINDICATIONS TO FERINJECT *

1. Anaemia not attributable to iron deficiency
2. Iron overload or disturbances in utilisation of iron.
3. Known hypersensitivity to Iron carboxymaltose (Ferinject®) or excipients (anaphylaxis has not yet been recorded, but resuscitation facilities for anaphylactic shock must be available where the drug is administered)
4. Clinical or biochemical evidence of liver damage
5. Acute/ chronic infection
6. First trimester of pregnancy

Appendix 3: Investigations in anaemic patients to confirm IDA and rule out other causes
Full blood count & film, reticulocytes, LFTs, ferritin, B12, folate, CRP

Appendix 4: Dosage of Ferinject®
- A single dose of Ferinject® must not exceed 20mg/kg (body weight) or 1000mg, whichever is less.
- If further iron carboxymaltose (Ferinject®) is required to reach the level of iron needed, wait for at least 1 week before giving the remaining dose
- Example 1: 40kg patient: dose of Ferinject® = 40x20 = 800mg single dose
- Example 2: 70kg patient: dose of Ferinject® = 70x20 = 1000mg initial dose + review in clinic to evaluate need for further 400mg dose

Appendix 5: Response to Ferinject®
Due to iron metabolic pathways, rise in reticulocyte count will occur during second week and thereafter, provided bleeding is not excessive, one can expect a rise in haemoglobin of approximately 1.5g/week. However response rates are very variable in individual patients, who can be discussed with haematology consultants for further advice.