Anaemia and use of oral iron supplements and Parenteral Iron in Pregnancy and the Postnatal Period – Guideline for Management

University Hospitals of Leicester NHS Trust

C1/2012

Contents

1. Introduction and Who Guideline applies to 1
WHAT'S NEW? 2
Related documents: 2
2. Guideline Standards and Procedures 3
Flowchart 1: Management of Anaemia in Pregnancy 3
2.1 Screening: 4
2.2 Assessment: 4
2.3 Treatment: 4
2.4 Monitoring: 5
2.5 Poor response/intolerance: 5
2.6 Absolute intolerance or non-compliance 5
2.7 Ferric Derisomaltose dosing and prescribing 5
Flow chart 2: Iron need more than the maximum dose 6
2.8 Ferric Derisomaltose administration: 6
Flow chart 3: Infusion Reaction Management 8
2.9 Post-natal anaemia: 9
3. Education and Training 9
4. Monitoring Compliance 9
5. Supporting References 9
6. Key Words 9
Appendix I: Dose and elemental iron content per tablet of combined oral iron and folate preparations 12
Appendix 2: Equipment required for administration of Parenteral Iron: 13
Appendix 3: Indications for assessment of serum ferritin 14
Appendix 4 – oral iron administration by community midwives 15
Flow chart 4: administering oral iron in the community 16
Appendix 5: Requesting a supply of oral iron and storage requirements 17
Appendix 6: GP letter 19
Appendix 7: Obstetric Haematology Nurse/Midwife led referral for parenteral iron infusion 20

1. Introduction and Who Guideline applies to

This guideline is aimed at all Health Care Professionals involved in the management of pregnant women and people with severe anaemia in pregnancy and the initial postnatal period.

Background:

Iron deficiency is the most common form of malnutrition in the world affecting more than 2 million people. Oral iron therapy and advice regarding dietary iron intake, are the simplest measures which can be employed to improve the haemoglobin (Hb) level. However, in the event that this is not possible there are alternatives. Although iron absorption from the diet increases three-fold in pregnancy, iron requirements increase even further and an iron deficit builds up.

Maternal anaemia has implications in pregnancy and postpartum period. Iron deficiency may contribute to maternal morbidity through effects on immune function with increased susceptibility or severity of infections (Eliz *et al,* 2005*)*, poor work capacity and performance (Haas *et al,* 2001) and disturbances of postpartum cognition and emotions (Beard *et al,* 2005).

It has been shown to increase the risk of postpartum haemorrhage (PPH) Please see Postpartum Haemorrhage UHL Obstetric Guideline. In a large prospective observational study at 2 maternity services in the UK found that 60% of women with Hb <85g/l sustained PPH, with a quarter progressing to severe PPH. One explanation is impaired uterine contractility due to reduced oxidative capacity. (Briley et al, 2014).

Evidence suggests that maternal iron depletion increases the risk of iron deficiency in the first 3 months of infant life, by a variety of mechanisms (Puolakka *et al*, 1980, Colomer *et al*, 1990). Impaired psychomotor and/ or mental development are well described in infants with iron deficiency anaemia and may also negatively contribute to infant and social emotional behaviour (Perez *et al,* 2005)

Intravenous iron is the chosen method of treatment for severe iron deficiency anaemia in pregnancy and the postnatal period. Intravenous iron can be used as a second line treatment when oral therapy is deemed inappropriate or has failed.

Parenteral Iron usage in pregnancy is limited. Ferric Derisomaltose is contraindicated in the 1st trimester of pregnancy, but may be used in the second and third trimester of pregnancy where the benefit outweighs the risk.

Definition:

There is variation in definition of normal haemoglobin levels in pregnancy. UK guidelines from the BCSH suggest definitions of anaemia as <110g/l in the first trimester and <105g/l in the second and third trimesters. Postpartum anaemia is defined as a haemoglobin <100g/l.

WHAT'S NEW?

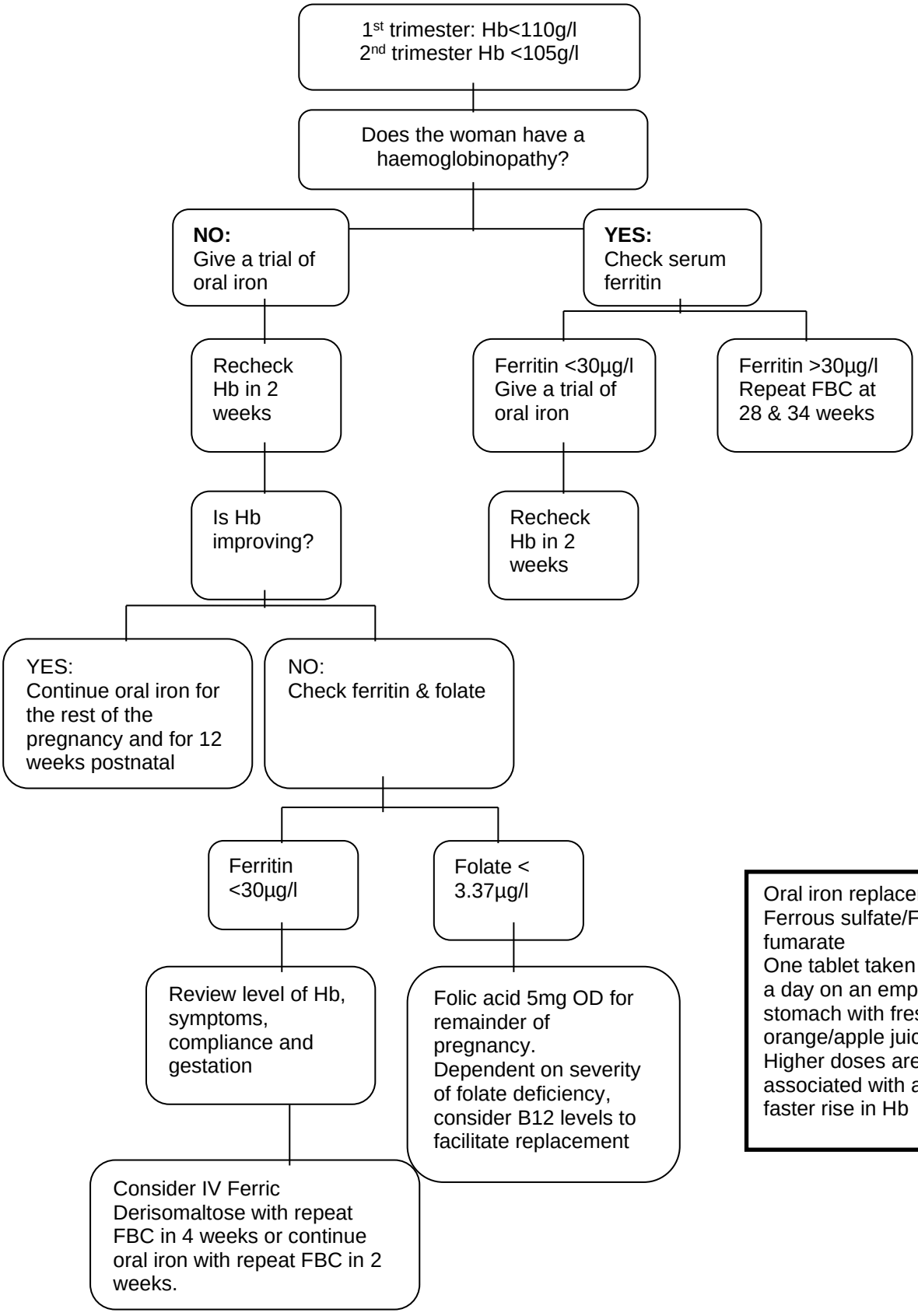
- **Ferinject® replaced by Ferric Derisomaltose ®**
- **Administration and dosing of Ferric Derisomaltose**
  - The dose of Ferric Derisomaltose should be calculated using the patient's **booking** body weight and haemoglobin (Hb) level
  - Fetal heart rate should be auscultated before and after administration.

Related documents:

- Booking bloods and urine test UHL Obstetric Guideline
- Sickle Cell and Thalassaemia (haemoglobinopathy) Screening in Pregnancy UHL Obstetric Guideline
- Aseptic Non Touch technique UHL Guideline
- Hand Hygiene UHL Policy
- MHRA Drug Safety Update, Volume 7,Issue 1 August 2013: Intravenous iron and serious hypersensitivity reactions: new strengthened recommendations to manage and minimise risk.
- Maternity Day Assessment Unit UHL Obstetric Guideline.pdf

2. Guideline Standards and Procedures

Flowchart 1: Management of Anaemia in Pregnancy



2.1 Screening:

- **All pregnant women and people** should have a screen for haemoglobinopathies at the first booking visit as per the guidelines for Sickle Cell and Thalassaemia. The result should be reviewed and documented in the health record.
- Pregnant women and people with known haemoglobinopathy should have assessment of serum ferritin and folate before supplements are commenced.
- All pregnant women and people should have a FBC taken at booking and at 28 weeks in accordance with NICE guidelines. The results should be clearly documented in the health care records at next antenatal clinic visit.

2.2 Assessment:

- All anaemic pregnant women and pregnant people should be contacted by the health care professional to assess wellbeing and if symptomatic clinical review arranged.
- All pregnant women and pregnant people with anaemia should be offered a trial of oral iron without delay (see 2.3 below).
- Non-anaemic pregnant women and pregnant people considered to be at risk of iron deficiency should have serum ferritin taken.
- **At risk pregnant women and pregnant people who are not yet anaemic should be given oral iron if ferritin level is <30ug/l.**

The clinical symptoms of iron deficiency anaemia in pregnancy are non-specific. Fatigue is the most common symptom but pregnant women and pregnant people may also present with pallor, weakness, headache, palpitations, dizziness, dyspnoea, irritability, and restless legs. A craving for non-food items such as ice (pagophagia) and soil (pica) may develop (Lumish et al, 2014).

2.3 Treatment:

- First line treatment for anaemia should be an oral iron only supplement such as Ferrous Fumarate 322mg. Pregnant women and pregnant people should be advised on the correct method of administration and also receive dietary advice (see appendix 4).
- Pregnant women and pregnant people who are confirmed on venous sampling to be anaemic and who do not have a known haemoglobinopathy should be commenced on oral iron therapy.
- Pregnant women and pregnant people who have either Thalassaemia trait or sickle cell trait should only be commenced on oral therapy if they have evidence of iron deficiency i.e. low serum ferritin.
- All pregnant women and pregnant people should be instructed regarding the correct way to take oral iron and dietary advice should be given. (see Anaemia leaflet)
- Oral iron should be taken on an empty stomach 1hour before or after food and should be taken with a vitamin C rich drink.
- If a pregnant woman or pregnant person is iron deficient prior to delivery and on iron therapy, they should continue oral iron for at least 3 months post-partum.

To ensure good compliance and minimize side effects, a once daily dose is advised. Higher doses potentially increase side effects such as gastric irritation, nausea and disturbed bowel function affecting compliance (Smith G. 2014 Cochrane database). Recent data has also shown that absorption of iron is maximized if given once daily rather than more frequently. (Moretti 2015)

2.4 Monitoring:

- Once treatment has been commenced a repeat FBC should be taken after 2 weeks.
- These results should be clearly documented in the pregnant woman's or pregnant person's health care records.
- If the Hb is improving treatment should continue. Further assessments of FBC may be required if there is concern about compliance, tolerance or significant anaemia (see appendix 4).

2.5 Poor response/intolerance:

- If there is no response after two weeks, if the Hb is not improving ferritin and folate levels should be checked and a referral should be made to secondary care.
- If after 2 weeks the FBC is not improving because there has been intolerable side effects limiting compliance, the pregnant woman or pregnant person should be given a different preparation of oral iron therapy e.g. Ferrous Sulphate or Sytron. (see appendix 4)
- If the pregnant woman or pregnant person has symptomatic anaemia, is over 34 week's gestation or is not tolerating any oral therapy then their Obstetric Lead Clinician should be consulted. If referring from the community, please contact your lead Obstetrician. If referring from MAU/Triage please contact the senior Obstetrician on the shift.

2.6 Absolute intolerance or non-compliance

- If there is absolute intolerance or non-compliance with oral iron, IV iron should be considered providing iron deficiency has been confirmed with a low serum ferritin.
- The decision to prescribe Parenteral Iron should be made by the Clinician following this guidance.
- Parenteral Iron **MUST NOT** be given in the first trimester of pregnancy

Indications for Parenteral Iron:

- Pregnant women and pregnant people with confirmed iron deficiency anaemia with a serum ferritin of <30ug/L who:

    1. Are intolerant to oral iron preparations or
    2. Fail to respond to oral iron therapy or
    3. Have malabsorption of oral iron

All care providers should discuss the option to use Parenteral Iron with the Lead Obstetric Clinician.

2.7 Ferric Derisomaltose dosing and prescribing

- The dose of Ferric Derisomaltose is expressed in milligrams of elemental iron. The dose of Ferric Derisomaltose should be calculated using the patient's **booking** body weight and haemoglobin (Hb) level.
- Ferric Derisomaltose should only be prescribed on the drug chart.
- Ideally, a prescription should be made at the time of arranging the infusion but if this is not possible it can be attained by the medical team that support MDAU (i.e. team on antenatal/postnatal wards or delivery suite).
- Dosing of Ferric Derisomaltose follows a stepwise approach
    1. Determination of the individual iron need - Table 1 provided (Use booking weight antenatally and actual weight postnatally).
    2. Calculation of the maximum iron dose(s) – Table 2.

3. Post-iron repletion assessments at least 4 weeks after administration of final infusion. These steps can be repeated if further iron required.

Table 1: Iron Need

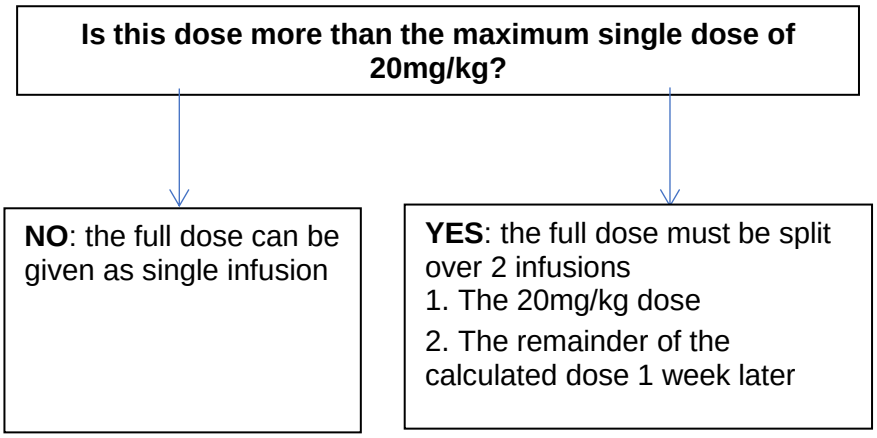
Hb (g/dL)	Body weight		
	<50 kg	50 kg - <70 kg	>70 kg
>/=100	500 mg	1000 mg	1500 mg
<100	500 mg	1500 mg	2000 mg

Maximum Iron Dose

- Calculation for maximum dose : 20mg iron/ kg body weight (this dose should not be exceeded)
- If the maximum dose calculated is less than the iron need (in Table 1), administer dose in single infusion

If the maximum dose calculated is more than the iron need (in Table 1) administer the dose in 2 separate infusions a week apart (see flow chart 2 below)

Flow chart 2: Iron need more than the maximum dose



Ferric derisomaltose is not recommended for use in children and adolescents < 18 years due to insufficient data on safety and efficacy.

2.8 Ferric Derisomaltose administration:

- Provide patient information leaflet and ensure that details of who to contact with any adverse reactions or queries is highlighted
- Avoid intravenous iron administration via cannulation at sites of flexion (e.g. antecubital fossa, wrist) or on the back of the hand
- The distal veins of the forearm are the preferred site. Use an appropriate cannula size (20- to 24-gauge)
- Secure the cannula and use an extension set to minimise catheter movement. Do not cover the injection site with a bandage
- Minimise the number of cannulation attempts
- Ensure the patency of the vein before administration. If patency is uncertain, do not administer intravenous iron
- Do not give infusions at night-time
- Do not give infusions to patients unable to report symptoms (e.g. anaesthetised)
- Ferric Derisomaltose should be administered as an infusion. (See Appendix 2)

- Ferric Derisomaltose should be diluted (volumes of 100 mls to no more than 250 mls of 0.9% sodium chloride)
- Doses up to 1000mg to be administered over 15 minutes
- Doses above 1000mg to be administered over 30 minutes
- A pump should be used to control the rate of infusion (initially a slower rate of infusion is suggested over the first 10 mins).
- No other therapeutic agents should be added to the infusion.
- Hypersensitivity reactions have also been reported after previously uneventful doses of parenteral iron complexes. Hypersensitivities have been noted with conditions that are immune related.
- The risk of hypersensitivity is enhanced with;
    1. Known allergies including drug allergies,
    2. History of severe asthma, eczema or other atopic allergy.
    3. Immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis).
- Patients should be closely monitored for signs of hypersensitivity (see appendix 1) during and for at least 30 minutes after every administration of an IV iron product.
- Fetal heart rate should be auscultated before and after administration.
- If signs of hypersensitivity have been experienced during the current or previous intravenous iron infusion administration, ensure the preparation that has triggered the reaction, is identified and documented in the hospital/electronic records
- Should there be an adverse reaction to the iron infusion, full assessment and monitoring will commence. This includes continuous fetal monitoring if gestation appropriate.
- Administration can only be undertaken in a clinical area where emergency equipment is available as there is a risk of anaphylaxis. The Maternity Day Assessment Unit has the ability to facilitate administration of Ferric Derisomaltose.
- The risk of anaphylaxis is very rare but it is recommended Adrenaline should be available as first line treatment in case of severe reaction.
- If Ferric Derisomaltose leaks out of the vein, it can cause skin staining. It is important to flush the cannula after insertion prior to commencing parenteral iron to ensure the cannula is correctly placed in the vein. (**please see patient information leaflet on YourHealth;** Treatment for low iron with an infusion)
- **Need for on-going iron supplements should be reviewed, depending on clinical circumstances. Further supplements should not be administered within a week of Parenteral Iron**
- **Follow-up FBC to be taken 4 weeks following infusion**

Flow chart 3: Infusion Reaction Management

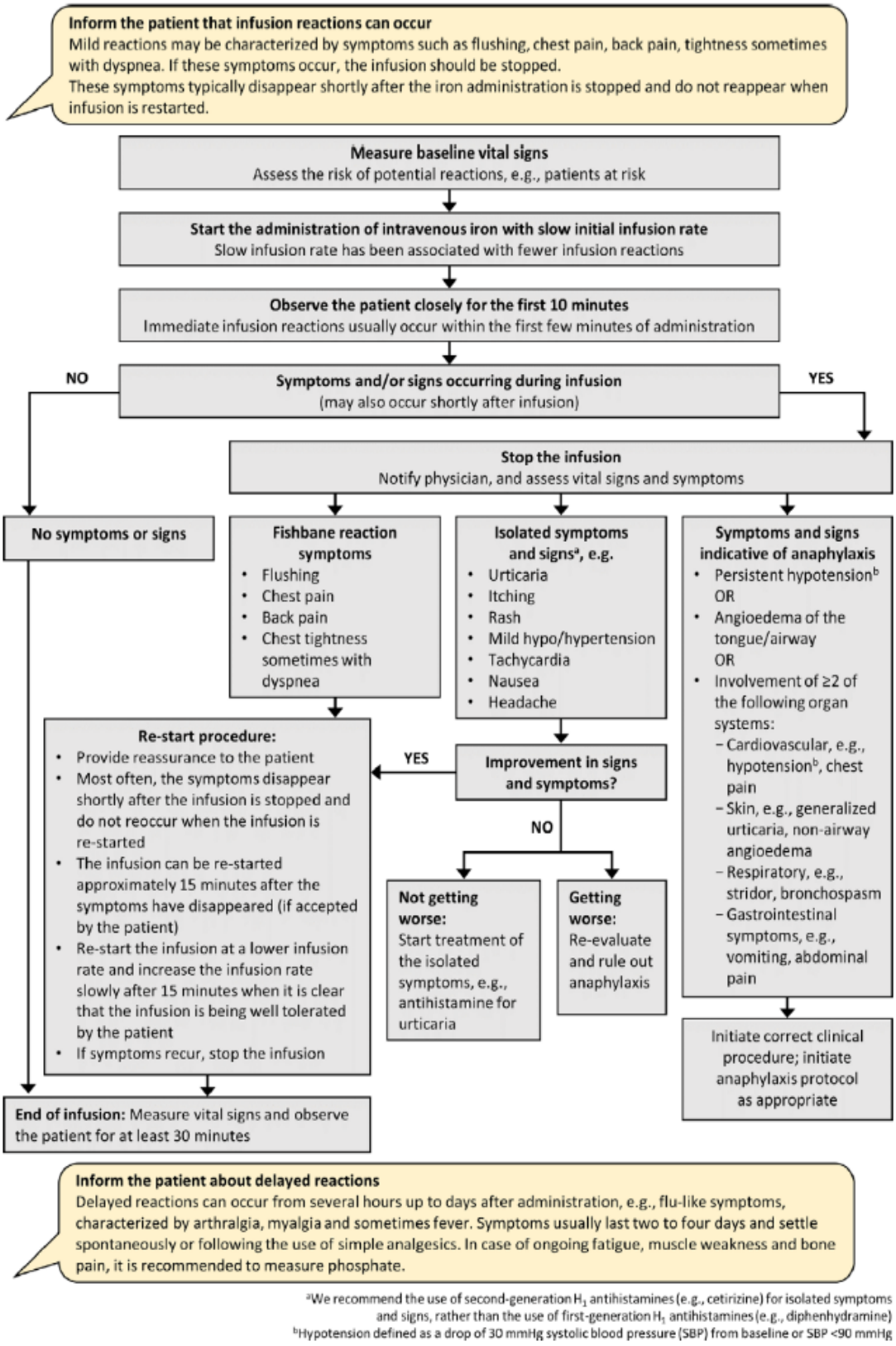


Fig. 2. Algorithm for the management of immediate infusion reactions. Adapted from: Rampton et al.,[4] Lim et al.,[22] Macdougall et al.,[23] and Simons et al.[24] [Color figure can be viewed at wileyonlinelibrary.com]

2.9 Post-natal anaemia:

- If the woman or birthing person is symptomatic in the postnatal period, but there is no on-going bleeding and there is no cardiovascular compromise parenteral Iron can be considered in an attempt to reduce transfusion of red cells.
- The same dosing and prescribing process should be used by using the current postnatal weight of the woman or birthing person.
- If there is on-going blood loss or any haemodynamic compromise, iron supplementation may well not be sufficient and the need for a blood transfusion should be discussed with the Obstetric Lead Clinician.

3. Education and Training

None

4. Monitoring Compliance

None

5. Supporting References

1. Briley et al., reporting errors, incidence &risk factors for PPH (prospective observational study) BJOG 214;121:876-888
2. Pena-Rosas, Juan Pablo, Luz Maria De-Regil, H. Malave Gomez, Monica C. Flores-Urrutia, and Therese Dowswell. "Intermittent oral iron supplementation during pregnancy." (2015): CD009997-CD009997.
3. Shinar S J, A Skornick-Rapaport, S Maslovitz. Iron supplementation in singleton pregnancy: Is there a benefit to doubling the dose of elemental iron in iron-deficient pregnant women? a randomized controlled trial. Journal of Perinatol 2017; 37: 782-786

   https://www.resus.org.uk/sites/default/files/2021-05/Emergency%20Treatment%20of%20Anaphylaxis%20May%202021_0.pdf

6. Key Words

Anaemia, Monofer®, Anaemia in pregnancy, Ferric Derisomaltose, Ferritin, Folate, Iron infusion

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The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

EDI Statement

We are fully committed to being an inclusive employer and oppose all forms of unlawful or unfair discrimination, bullying, harassment and victimisation.

It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristic: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and colour), Religion or Belief, and beyond.

We are also committed to the principles in respect of social deprivation and health inequalities.

Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) N Archer - Consultant **Original Authors**: P Coser, L Matthews, M Copple, C Oppenheimer, H Maybury, S Pavord, K Longmuir and L Sanders	**Executive Lead** Chief Medical Officer

Details of Changes made during review:

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
January 2022	**3**		Added consideration of Other preparations of IV iron use such as Monofer Added MAU now have daily slots Mon-Fri for administering IV infusion Removed Vit b12 pathway from the flowchart in Appendix 4 (UHL lab doesn't measure accurately the Vit B12 component levels that would alter management in pregnancy) Appendix 4 folate level change from <2ng/ml to < 2.6 Updated anaphylaxis treatment in line with Resuscitation Council UK 2021
June 2022	**v3.1**		Added specialist nurse/midwife referral for parenteral iron infusion criteria to appendix 5 Added HaemObs email
January 2023	**v3.2**		If the Ferinject® leaks out of the vein, it can cause skin staining. It is important to flush the cannula after insertion prior to commencing Ferinject® to ensure the cannula is correctly placed in the vein Added common or very common side effects
October 2023	**4**		Added statement - to document any adverse reactions to medical records & to provide PIL
April 2024;	**5**		Removed pregaday from treatment options
May 2024:	**5**		Added further cannulation insertion and care advice to minimise the risk of cannula failure and extravasation. Added follow-up FBC to be taken 2-4 weeks post infusion

December 2024	**6**	**Maternity guidelines group** **Maternity Governance committee**	**Removed reference to Ferinject, replaced with parenteral iron or Ferric Derisomaltose** **Dosing and administration details updated in line with Ferric Derisomaltose.** **Removed refer to Haematological Obstetric Team in cases where parenteral iron supplementation is being considered, refer to Consultant Obstetrician only.** **Hyperlinked to MDAU SOP.** **Added that fetal heart auscultation needs to be performed pre and post parenteral iron infusion.** **Updated keywords** **Added community iron provision guidance and process to appendix** **Sign posted to PIL.**

Appendix I: Dose and elemental iron content per tablet of combined oral iron and folate preparations

Combined iron and folate preparation	Iron salt and dose per tablet	Elemental iron content per tablet	Folic acid content per tablet
Fefol	Sulphate 325 mg	47 mg	500 mcg
Galfer FA	Fumarate 305 mg	100 mg	350 mcg
Systron	Feredetate 190mg/5 mls elixir	27.5mg/ 5mls elixir	None
Ferrous Sulphate	200 mg	65 mg	None

Appendix 2: Equipment required for administration of Parenteral Iron:

Ferric Derisomaltose doses up to 1000mg to be given over 15 mins.
Ferric Derisomaltose doses above 1000mg to be administered over 30 mins

1 alcowipe
1 green Venflon.
Tape or cannula dressing
Vacutainer blood bottles- FBC.
2 White needles.
1 x 5 ml syringe
1 x 20 ml syringe
5mls of 0.9% sodium chloride (to flush the cannula)0.9% sodium chloride volumes of 100 - 250 mls.
Giving set (appropriate giving set to use with correct pump)
Gauze.

Procedure for administration of Parenteral iron infusion.

Baseline observations4
Fetal heart rate should be auscultated before and after administration
Prepare infusion of Ferric Derisomaltose
Prepare the skin in accordance with the aseptic non touch technique policy.
Insert venflon according to UHL guidelines.
Secure cannula in position with tape or cannula dressing.
Take blood as required via the cannula.
Flush with 2mls of 0.9% sodium chloride.
Connect infusion of and infuse via pump calculated to the correct rate for the infusion.
Observe patient for any adverse events.
During infusion monitor observations **every 15 minutes and 30 minutes after the completion of the infusion**
Should there be an adverse reaction to the iron infusion, full assessment and monitoring will commence. This includes continuous fetal monitoring if gestation appropriate.

Remove cannula following completion of infusion.
Post infusion observations.

IM/IV Adrenaline should be available for immediate use in the event of a severe adverse drug reaction.

Appendix 3: Indications for assessment of serum ferritin

Anaemic pregnant women or pregnant people where estimation of iron stores is necessary

Known Haemoglobinopathy
Prior to parenteral iron replacement

Non-anaemic pregnant women or pregnant people with high risk of iron depletion

Previous anaemia
Multiparity >=P3
Consecutive pregnancy <1year following delivery
Vegetarians
Teenage pregnancies
Recent history of bleeding

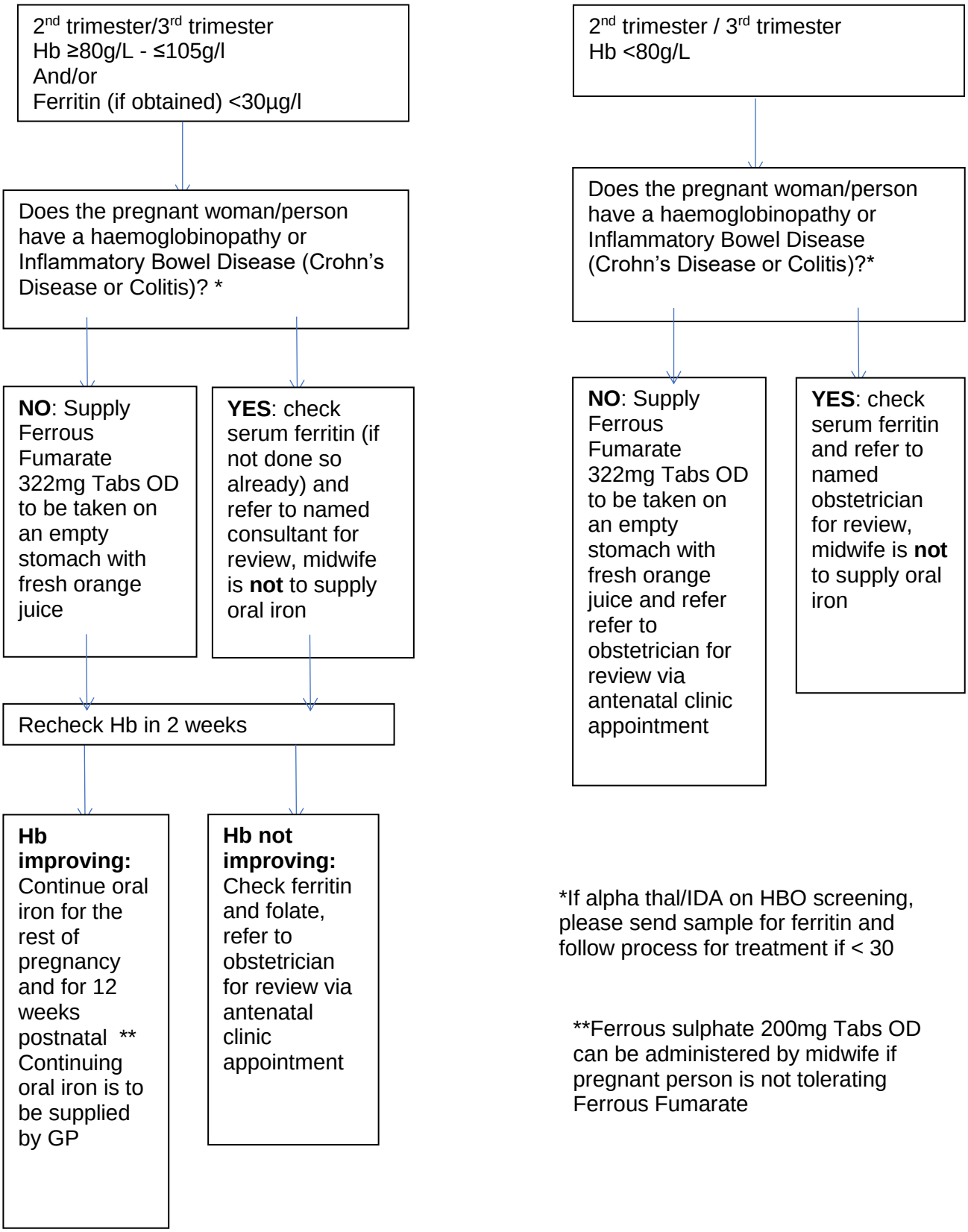
Non-anaemic pregnant women or pregnant people where estimation of iron stores is necessary

High risk of bleeding
Those declining blood products

Appendix 4 – oral iron administration by community midwives

Under PRESCRIBING (leicestershospitals.nhs.uk) guideline, midwives can administer, carry and supply Ferrous Fumarate Tabs 322mg and Ferrous Sulphate Tabs 200mg.
This document and flow chart will be added to PRESCRIBING (leicestershospitals.nhs.uk) to guide midwives in appropriately administering and supplying oral iron. Midwives should only supply and administer the first dose if oral iron, any subsequent doses must be provided through the GP. This guidance is to prevent a delay in oral iron being administered and is not intended as replacement method of repeat prescriptions.
This document should be read alongside the Anaemia and the use of iron supplements and parenteral iron infusion in Pregnancy and the Postnatal Period Guideline.
Blood results should be chased within 14 working days to support timely management of findings. If oral iron is required, the midwife must contact the patient to arrange for timely collection of the oral iron and discuss how to take this and document discussions.

Flow chart 4: administering oral iron in the community



*If alpha thal/IDA on HBO screening, please send sample for ferritin and follow process for treatment if < 30

**Ferrous sulphate 200mg Tabs OD can be administered by midwife if pregnant person is not tolerating Ferrous Fumarate

Appendix 5: Requesting a supply of oral iron and storage requirements

Order oral iron via pharmacy. This will be completed by Maternity Admin Supervisor.
Oral iron will be delivered to Community Midwives Office via pharmacy and stored in the medicine cabinet in the Community Office at LGH.
A nominated community midwife from each team will collect their team's supply of oral iron and deliver them to their hub to be stored in their hubs allocated locked medicine cabinet. **Note**: MSW's are **not** permitted to carry the medication and so **must not** be delegated to due this duty on a midwives behalf.
Community midwives are able to carry the oral iron in their car which is insured with business insurance. The oral iron must be kept out of sight during transportation e.g. in the boot of car in the midwives work bag. At all other times the bag must be securely stored in the registered midwife's home in a secure locked fixture. This is in line with Chapter 16 Leicestershire Medicines Code Supply and Administration of Medicines by Midwives.
Any excess oral iron in the community midwives possession must be returned to the hub during period of long absence e.g. annual leave
Oral iron provided to a patient by the midwife must be clearly documented as 'supplied through midwives exemption'.

Table a: storage of oral iron for each community team

Community Team	Location of storage
Abbey	Loughborough Hospital
Evington	Community Midwives Office LGH
Woodland	Fleckney Hub
Belmont	Community Midwives Office LGH
Mallory	Hinckley Health Centre
Meridian	Gallards Children Centre
Homebirth team	Homebirth team office at Glenfield Hospital
Rutland teams	St Mary's Birth Centre

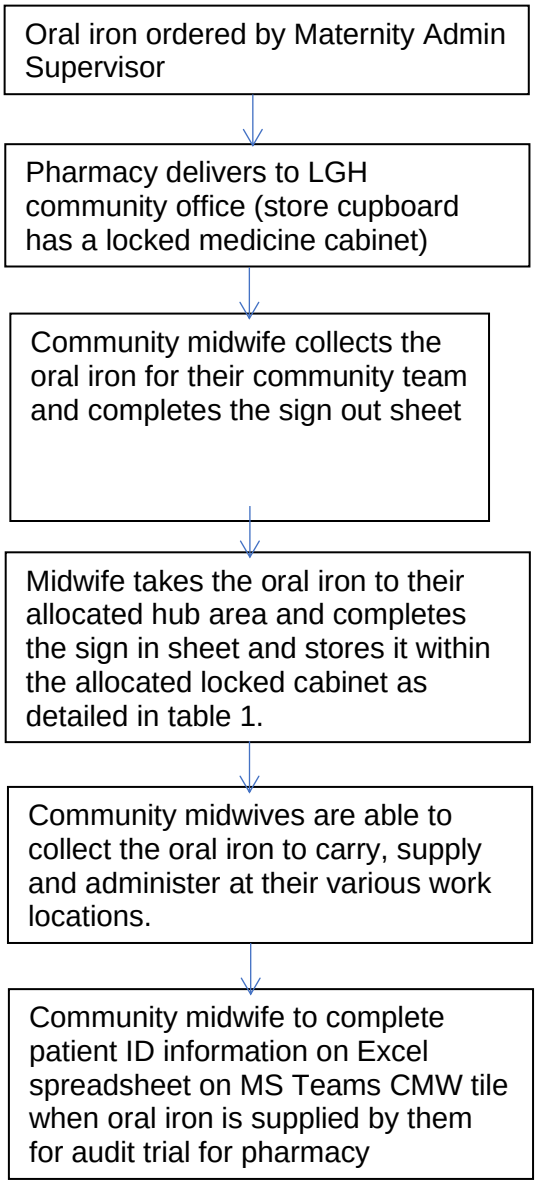
Community midwives to obtain oral iron from the storage place for supply in their antenatal clinics.

Table b: allocated oral iron per team

1 box is 28 tablets of Ferrous Fumerate 322mg.

Community Team	allocated oral iron per team per month
Abbey	25 boxes
Evington	40 boxes
Woodland	40 boxes
Belmont	20 boxes
Mallory	35 boxes
Meridian	40 boxes
Homebirth team	5 boxes
Rutland teams	15 boxes

Flow chart 5: ordering process and audit



Appendix 6: GP letter

University Hospitals of Leicester NHS Trust

Name: NHS number: DOB:

Date:

Dear Dr _____

The above patient has been advised to take Ferrous Fumarate 322mg Tabs OD / Ferrous Sulphate 200mg Tabs OD until 12 weeks postpartum. This is in line with the 'Anaemia and Use of Iron supplements and Parenteral Iron in pregnancy UHL Obstetric Guideline'.
They are currently ____ weeks pregnant, their haemoglobin is _____g/L
Please provide them with a repeat prescription until 12 weeks postpartum which is anticipated to be on _____

Kind regards,

Appendix 7: Obstetric Haematology Nurse/Midwife led referral for parenteral iron infusion

Registered midwives can arrange IV iron with MAU once approved by lead obstetric clinician or HaemObs team.

An obstetric haematology nurse or obstetric haematology specialist midwife can directly arrange an IV iron infusion without medical review if following criteria is met:

- Gestation 34/40 or higher
- Patient have no haemoglobinopathies - if present medical review needed
- Hb < 90g/l
- Iron deficiency confirmed
- Ferritin level <30 within last 4 weeks
- Folate level checked
- If Folate < 3.37 µg/l ensure that Folic Acid 5mg once a day dose prescribed
- No contraindications or allergy to IV iron
- Stop oral iron for 1 week