Northern Devon Healthcare NHS Trust

Document Control

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Iron Deficiency Anaemia in Pregnancy			
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1.0	Aug 2013	Final	Rejected by maternity services guideline group
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Superseded Documents N/A			
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Consulted with the following stakeholders:

- Senior Midwives
- Obstetricians and Gynaecologists
- Haematology /Blood transfusion service
- Pharmacists
- Drug& Therapeutic Committee

Approval and Review Process

- Maternity Services Governance Forum

Local Archive Reference

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Local Path

Antenatal clinic /Policies and Guidelines

Filename

Iron Deficiency Anaemia in Pregnancy

Policy categories for Trust's internal website (Bob)	**Tags for Trust's internal website (Bob)**
Maternity Services	Pregnancy, Iron deficiency, anaemia

Northern Devon Healthcare NHS Trust

CONTENTS

1. Purpose

1.1. Iron deficiency is the most common deficiency state in the world, affecting more than 2 billion people globally. Although it is particularly prevalent in less-developed countries, it remains a significant problem in the developed world, even where other forms of malnutrition have already been almost eliminated. Effective management is needed to prevent adverse maternal and pregnancy outcomes, including the need for red cell transfusion.

1.2. This document sets out Northern Devon Healthcare NHS Trust's best practice guidelines for the management of iron deficiency anaemia in pregnancy.

1.3. The purpose of this document is to provide healthcare professionals with a frame work for the diagnosis and management of iron deficiency in pregnancy and the postpartum period.

1.4. The following general principles were developed in accordance with best practice guidance developed by the British Society for Haematology, Obstetric Haematology Group and the British Committee for Standards in Haematology.

1.5. This guideline applies to maternity team and must be adhered to. Non-compliance with this guideline may be for valid clinical reasons only. The reason for non-compliance must be documented clearly in the patient's notes.

2. Definitions /Abbreviations

CMW Community midwife

FBC Full blood count

Hb Haemoglobin

MCV Mean cell volume

MCHC Mean cell haemoglobin concentration

IDA Iron deficiency anaemia

IV Intravenous

3. Responsibilities

3.1. It is the duty of all health care professionals to be able to detect early, and manage appropriately, iron deficiency in pregnancy. This may prevent otherwise young and healthy patients from receiving an unnecessary blood transfusion.

3.2. Medical Staff

- It is the referring doctor's (SAS doctor or consultant) responsibility to ensure that treatment with intravenous iron is appropriate after risk-benefit assessment and other causes of anaemia have been excluded using antenatal anaemia pathway.

3.3. Midwifery staff

- Undertake appropriate monitoring of observations before, during (every 15 mins) and after (every 15 mins for 30 mins) infusion and record on MEOWS chart.

- Document the details of this clinical episode in the woman's healthcare records including: attendance, observations, patient status, events of admission including complications, confirm provision of patient information leaflet on iron deficiency anaemia, discussion of risks & benefits, informed consent and provide emergency contact details.

4. General Principles of Management of Iron Deficiency Anaemia in Pregnancy

4.1. Definition of anaemia

- Anaemia is defined as Hb less than 2 standard deviations below the mean for a healthy matched population.

- Anaemia in pregnancy is defined when Hb <110g/l in first trimester, <105g/l in second and third trimesters and <100g/l in postpartum period.

4.2. Diagnosis of iron deficiency anaemia in pregnancy

4.2.1. Clinical symptoms and signs

a. Clinical symptoms and signs of iron deficiency anaemia in pregnancy are usually non-specific, unless the anaemia is severe. Fatigue is the most common symptom. Patients may complain of weakness, headache, palpitations, dizziness, dyspnoea, fainting and lethargy. Rarely pica develops, where there is a craving for non-food items such as ice and dirt. Iron deficiency anaemia may also impair temperature regulation and cause pregnant women to feel colder than normal.

b. Iron stores are depleted before a fall in Hb and as iron is an essential element in all cells, symptoms of iron deficiency may occur even without anaemia: These include fatigue, irritability, poor concentration and hair loss.

4.2.2. Laboratory tests

a. Full blood count, blood film and red cell indices.

- A full blood count (FBC) may show low haemoglobin (Hb), mean cell volume (MCV), mean cell haemoglobin (MCH), and mean cell haemoglobin concentration (MCHC); a blood film may confirm presence of microcytic hypochromic red cells and characteristic 'pencil cells'.

- Iron deficiency anaemia can at times be present in the absence of a low Hb and can be diagnosed by a full blood count with a reduced MCV and MCHC. In these circumstances, a ferritin should be checked and if<30u/l, iron therapy should be commenced as outlines below.

b. Serum ferritin

- Serum ferritin accurately reflects iron stores in the absence of inflammatory change (Concurrent measurement of the C-reactive protein (CRP) is helpful in interpreting higher levels where indicated, as the serum ferritin levels will rise when there is active infection or inflammation). Serum ferritin <30µg/l indicates iron depletion in all stages of pregnancy and should prompt treatment.

c. Following laboratory tests are not routinely measured.

Serum iron (Fe) and total iron binding capacity (TIBC).
Zinc protoporphyrin (ZPP).
Soluble transferrin receptor (sTfR).
Reticulocyte haemoglobin content and reticulocytes.

4.2.3. Trial of iron therapy

- A trial of iron therapy is both therapeutic and diagnostic. Patients with microcytic or normocytic anaemia can be assumed to be caused by iron deficiency until shown otherwise. Following 2 weeks of oral iron therapy, a rise in Hb should be demonstrated to confirm iron deficiency anaemia.

4.3. Management of Iron deficiency anaemia in pregnancy (APPENDIX 2)

- Routine iron replacement in pregnancy is not recommended. All women should have a blood test for FBC taken at the booking appointment and at 28 weeks (NICE).

- Health-care professionals requesting the blood tests must review the results, preferably within 72hrs and inform the women with an appropriate plan of management to avoid delays in treatment.

4.3.1. Oral Iron Treatment

- Women with Hb <110 g/l before 13 weeks or <105 g/l beyond 13 weeks, a trial of oral iron should be commenced as the first line treatment for anaemia, providing haemoglobinopathy has been excluded. An increase in Hb must be demonstrated at 2 weeks, otherwise further tests are required.

- **Serum ferritin** should be checked first in patients with haemoglobinopathy.

  Serum ferritin level may be checked, in the following conditions, and therapeutic iron should be considered if the ferritin is <30 µg/l.

  Normal Hb but low MCV&MCHC.

  High risk of iron depletion such as those with previous anaemia, multiple pregnancy, multiparity =/>3, consecutive pregnancies with less than a year's interval between, and vegetarians.

  Where estimation of iron stores is necessary such as those with a high risk of bleeding and Jehovah's Witnesses

- The oral dose for iron deficiency anaemia should be 100-200 mg of elemental iron daily. Treatment should start promptly in the community and women should be advised not to take iron tablets or iron-rich food with substances which inhibit its absorption, such as antacids, tea, coffee, milk, eggs and foods rich in calcium, zinc, phosphorus.

- First line of treatment is ferrous sulphate or ferrous fumarate.

Preparations of oral iron supplements

Preparation	Dose per tablet	Elemental iron
Ferrous Fumarate	210mg	65mg
Ferrous Gluconate	300mg	35mg
Ferrous Sulphate	200mg	65mg
Ferrous Feredetate (Sytron)	190mg/5ml elixir	27.5mg/5ml elixir
Pregaday(Fumarate)	100 mg	

- Women should be counselled how to take oral iron correctly. **This should be on an empty stomach, 1 hour before meals, with a source of vitamin C such as orange juice to maximise absorption.** Other medications or antacids should not be taken at the same time.

- For women who suffer with nauseas and epigastric discomfort, preparations with a lower iron content should be tried. Slow release and enteric coated forms should be avoided.

- Women should also be encouraged to take iron rich food sources such as red meat, fish, poultry, spinach etc.

- Repeat haemoglobin testing is required 2 weeks after treatment for established anaemia, to assess response to treatment and ensure

compliance and correct administration. The timing of further checks will depend upon the degree of anaemia and gestation.

- Referral to consultant led antenatal clinic should be considered if advanced gestation (36 weeks and above) or if there is no rise in Hb at 2 weeks. Referral to a haematologist should be considered if there are significant symptoms and or severe anaemia (Hb<70g/l).
- Once the Hb concentration is in the normal range, iron supplementation should be continued for 3 months and at least 6 weeks postpartum to replenish iron stores.

4.3.2. Parental Iron Therapy

- Studies have shown a faster increase in the haematological parameters (haemoglobin, haematocrit, ferritin, reticulocyte count) with IV iron therapy compared to oral iron. However, there are no adequate and well-controlled trials of parental iron therapy in pregnant women. A careful risk/benefit evaluation is therefore required before use during pregnancy and Iron infusion should not be given during pregnancy unless clearly necessary.

- ***Iron isomaltoside 1000 (Monofer®)*** is the intravenous iron preparation of first choice. Compared to other preparations, it has the advantages of higher availability for erythropoiesis, and a better safety profile in pregnancy.

A. <u>Indications in pregnancy and postnatal period include:</u>

- Failure of IDA in pregnancy to respond to oral iron therapy for 2 weeks.
- As second line treatment when oral iron therapy is deemed inappropriate, either because of poor tolerance, unacceptable side effects, absolute non-compliance or proven malabsorption.
- Where there is lack of time for an adequate course of oral iron (i.e. after 36 weeks gestation) and where blood transfusion is contraindicated.
- Postpartum anaemia when a more rapid increase in haematological parameters is desired e.g. following postpartum haemorrhage with Hb in approximate range 70-90 g/l and mild symptoms of low Hb (such as fatigue or dizziness are present).
- Blood transfusion is declined e.g. Jehovah's Witness

B. <u>Contraindications for parenteral iron infusion are</u>

- Use during the 1st trimester of pregnancy
- Non-iron-deficiency anaemia
- Iron overload or disturbances in utilisation of iron (e.g. hemochromatosis, haemosiderosis).

- A history of serious hypersensitivity to parenteral iron preparations
- Clinical or biochemical evidence of liver damage
- Parenteral iron should be used with caution in case of acute or chronic infection. It should not be used in patients with on-going bacteraemia.
- Patients with thalassaemia or sickle cell disease should NEVER routinely receive iron therapy either oral or intravenous. However, those diagnosed with IDA should be reviewed for appropriate management and treatment.

C. Organising Monofer infusion

- The decision for an iron infusion must be made by the SAS Doctor/ Consultant.
- The indication, side effects, mode and frequency of delivery of Monofer should be discussed with the mother before commencement of treatment and clear documentation in the notes is necessary.
- Ensure up to date Haemoglobin level (within 7 days prior to infusion)
- Once the decision has been made, women should be advised not to take their oral iron tablets for 24 hours pre- infusion and 5 days post infusion.
- **To reduce the risk of hypersensitivity reaction, prescribe Chlorpheniramine 4mg po to be taken at least 2 hours pre-infusion. Alternatively, woman can buy it over the counter.**
- Women should be asked to attend the central delivery suite for the infusion at a mutually convenient time, as arranged at initial consultation. On arrival to Labour ward, the co-ordinator may decide on the best location for the iron infusion.

D. Calculating dose

- The online calculator is no longer available -See **Appendix 5.**
- In left hand column, find the pre-pregnancy body weight of the patient.
- Read across this row to the column headed by the haemoglobin value that matches the patient's current state. The reading at this point is the dose required expressed as mg of iron. Monofer provides 100 mg iron per mL of solution. Therefore, if the result is 675, add 6.75 mLs of Monofer into 100 mLs normal saline.
- Dilute the monofer dose into 100 mLs normal saline and infuse over 60 minutes

- If the dose that you arrive at is in bold, then it must be divided for administration because it is above the upper limit of 20mg/kg body weight for total dose infusion. Give half the dose and allow 2 weeks before giving the other half of the dose.

E. Administration

1. Before commencement of treatment, check the patient has not taken oral iron in previous 24 hours. **Make sure the patient takes Chlorpheniramine 4mg po at least 2 hours pre-infusion**

2. Patient should be thoroughly informed of the relevant symptoms of hypersensitivity and advised to tell the doctor or midwife straight away if any of these occur.

3. Clear documentation of informed consent in the notes is necessary.
4. Record baseline observations: temperature, pulse, respiration, blood pressure; on the MEOWs chart.

5. Inform the SAS doctor before proceeding with the iron infusion

6. There is no requirement for a test dose.

7. Monofer should only be administered by a trained midwife or medical staff.

8. Check adult resuscitation / anaphylaxis equipment.

9. Obtain IV access – avoid flexor points (antecubital fossa)

10. From a microbiological point of view, once made up, the product should be used immediately.

11. Monitoring should be continued at every 15 mins' interval (with continuous SaO2) during infusion until 30 mins' post infusion. Fetal monitoring is not required during the infusion. Monitor IV site for any signs of extravasation (leakage of drug into the tissue).
12. Flush the cannula with 10mls 0.9% sodium chloride prior to removal.

13. Women can go home 30 mins after the infusion if observations are stable.

14. If appropriate, commence oral iron therapy, at least 5 days after the last injection of Monofer®.

15. After infusion, blood tests (Hb & ferritin) on 2 weeks post infusion will be organised on the day of infusion.

16. A failure to increase Hb may be a result of fetal demand for physiological iron and is not a treatment failure. In this situation, haematologist advice may need to be sought depending on the gestation.

17. In the postnatal period check FBC and Ferritin at 6 weeks' post administration.

F. Complications

- **Hypersensitivity reactions** including serious and potentially fatal anaphylactic/anaphylactoid reactions. (**see Appendix 1& 4**)
- 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, patients with a history of severe asthma, eczema, other atopic allergy or in patients with immune or inflammatory conditions (e.g. systematic lupus erythematosus, rheumatoid arthritis)
- Ensure fetal heart rate by CTG is monitored when reaction is suspected.
- Following moderate or severe reaction, patients will need a Triptase test to confirm anaphylaxis (Type-1 IgE) versus CARPA (complement activation-related pseudo allergy) to plan for future treatment.
- **Extravasation** - Extravasation of all forms of IV iron therapy may result in permanent skin pigmentation and skin irritation. Iron should therefore only be transfused via larger visible veins and if any symptoms or signs of extravasation are suspected the infusion should be discontinued immediately. Treatment is dependent on the severity of the extravasation and should be determined before removal of the cannula; advice may be sought from the Pharmacy Department. All incidents of extravasation should be documented in the patient's notes and a datix incident form completed.

4.3.3. Blood Transfusions

- Prompt recognition of iron deficiency in the antenatal period followed by iron therapy may reduce the subsequent need for blood transfusions.
- Blood transfusion should be reserved for patients at risk of further bleeding, with imminent cardiac compromise or with symptoms requiring urgent attention.
- Women receiving red cell transfusion should be given full information regarding the indication for transfusion and alternatives available. Consent should be sought and documented in the clinical notes.

4.4. Care of Women with Iron Deficiency Anaemia in Labour

- Women with Hb < 100 g/l are regarded as high risk and should be advised to deliver at the hospital.
- On admission in labour, IV access should be obtained, and bloods taken for FBC & G&S.

- Active management of third stage of labour is advised. This should be with intramuscular syntometrine/syntocinon and in the presence of additional risk factors, such as prolonged labour or instrumental delivery, an intravenous infusion of high dose syntocinon continued for 2-4 hours to maintain uterine contraction.

4.5. Postnatal anaemia (see APPENDIX 3)

- In the postpartum period, FBC should be checked within 48 h of delivery in all women with an estimated blood loss >500 ml and in women with uncorrected anaemia in the antenatal period or symptoms suggestive of postpartum anaemia.

- Women with a **Hb level 80-100 g/L,** who are haemodynamically stable, asymptomatic, or mildly symptomatic, should be offered Ferrous Sulphate 200mg bd for 3 months, with repeat FBC and serum ferritin at the end of treatment to ensure Hb and iron stores are replete. Women with Hb <100 unable to tolerate or oral iron may also be offered parenteral iron.

- Monofer infusion should be considered for asymptomatic women with **Hb level 70-79 g/l,** and FBC and ferritin should be checked at ten days to ensure response to treatment, and again at 3 months to ensure iron stores replete.

- For symptomatic women with **Hb level <70g/l,** red cells transfusion should be considered following discussion with consultant/SAS obstetrician. FBC should be re-checked before discharge and 6 weeks postnatal after transfusion.

5. Education and Training

- Registered midwives and medical staff caring for women with anaemia in pregnancy have a professional responsibility to maintain their competence.

- Parenteral iron infusion 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.

- Training on parental infusion of Iron Isomoltoside 1000 will be provided by a specialist transfusion staff from the trust in conjunction with Pharmacosmos UK Ltd.

6. Consultation, Approval, Review and Archiving Processes

- The author consulted with all relevant stakeholders. Please refer to the Document Control Report. Final approval was given by the Maternity Services Guideline Group.

- The guidelines will be reviewed every 3 years. The author will be responsible for ensuring the guidelines are reviewed and revisions approved by the Maternity Services Guideline Group in accordance with the Document Control Report.

- All versions of these guidelines will be archived in electronic format by the author within the Maternity Team policy archive.

- Any revisions to the final document will be recorded on the Document Control Report. To obtain a copy of the archived guidelines, contact should be made with the Maternity Services Guideline Group.

7. Monitoring Compliance and Effectiveness

- Monitoring of implementation, effectiveness and compliance with this guideline will be the responsibility of the senior management team and maternity services risk co-ordinator. Where non-compliance is found, it must have been documented in the patient's medical notes.

- Adverse events should be reported to MHRA (Medicines and Health Care Products Regulatory Agency) at ***www.mhra.gov.uk/yellowcard*** and to Pharmacosmos UK Ltd at ***pvuk@pharmacosmos.co.uk.***

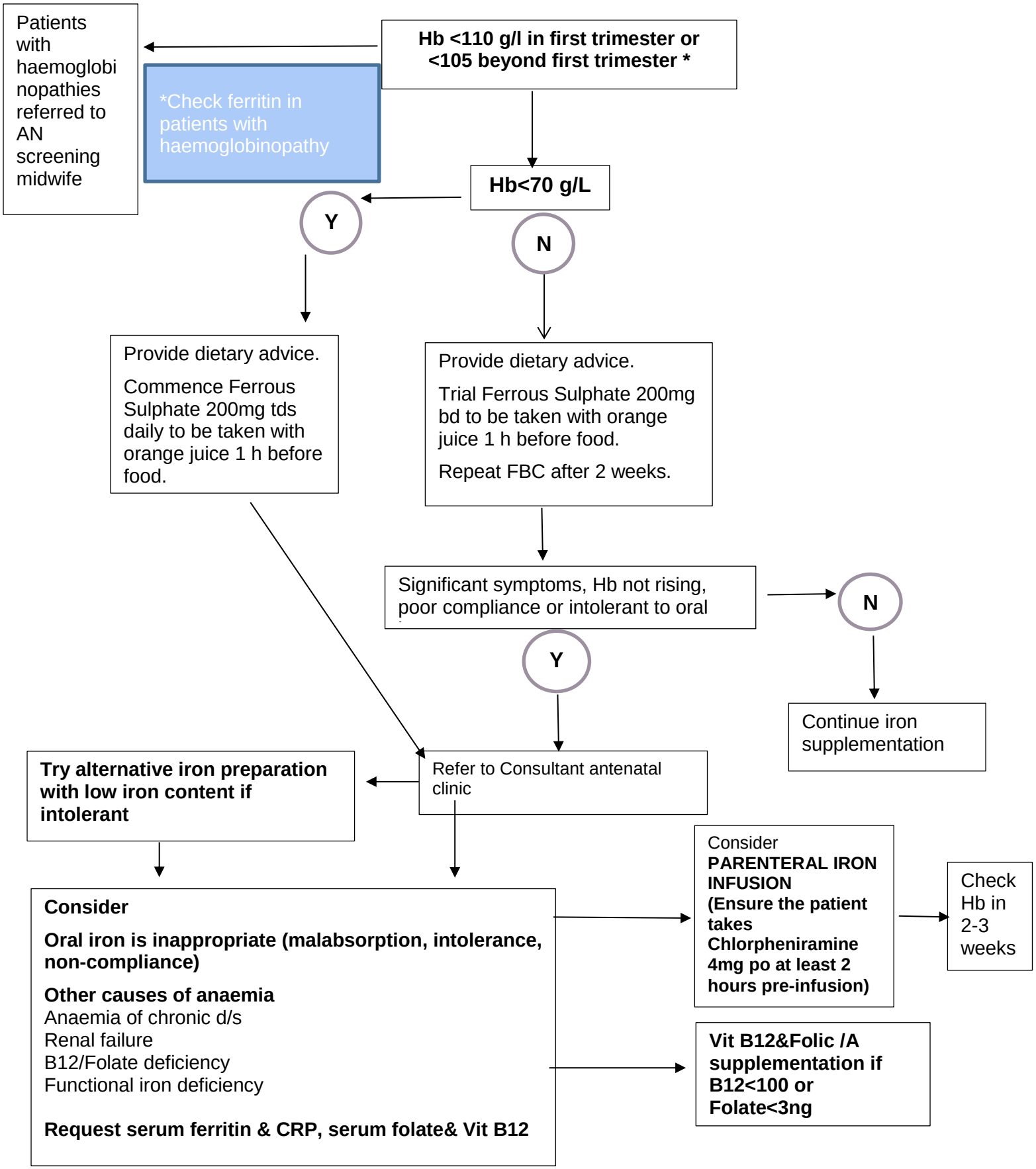
8. References

- Pavord S, Myers B, Robinson S, Allard S, Strong J, Oppenheimer C: UK guidelines on the management of iron deficiency in pregnancy: Br J Haematol 2012;156(5):588-600.
- National Institute for Health and Clinical Excellence (NICE) guideline Antenatal care on uncomplicated pregnancies. CG62; March 2008.
- South West Regional Transfusion Committee. Regional template/guideline for the management of anaemia in pregnancy and postnatally. April 2014
- Bayoumeu, F et al. 2002. Iron therapy in iron deficiency anaemia in pregnancy: intravenous route versus oral route. Am J Obstet&Gynae;186(3).
- Bhandal, N.2006. Intravenous versus oral iron therapy for postpartum anaemia. British Journal of Obstetrics & Gynaecology,113(11),1284-1252.
- Intravenous iron and serious hypersensitivity reactions: new strengthened recommendations to manage and minimise risk. MHRA Drug Safety Update, Volume 7, Issue 1, August 2013.
- Royal College of Obstetricians and Gynaecologists (RCOG) Blood Transfusion in Obstetrics. Green-top Guideline No. 47; May 2015
- Resuscitation Council (UK) www.resus.org.uk
- Iron isomaltoside 1000 (Monofer®) Summary of Product Characteristics – (http://www.medicines.org.uk/emc/medicine/23669/SPC/Monofer+100mg+ml+solution+for+injection+infusion/)
- A model treatment protocol for the administration of total dose infusion of MonoFer® (July 2016, Pharmacosmos**)**
- Royal Devon and Exeter NHS Foundation Trust, Clinical guideline for “Anaemia in pregnancy”; January 2017.
- Royal Devon and Exeter NHS Foundation Trust, Clinical guideline for “Iron infusion in pregnancy”; February 2017.

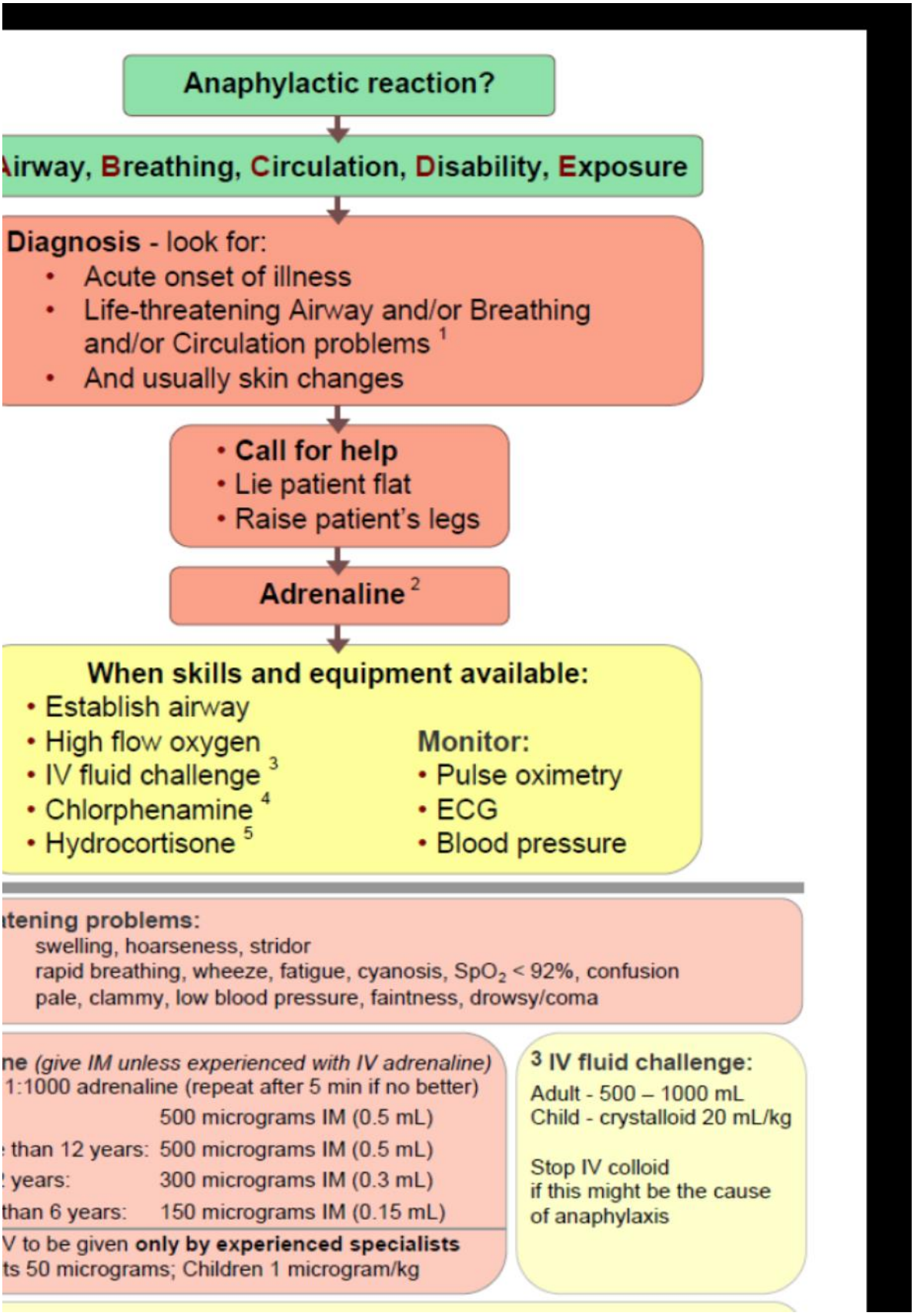
9. Associated Documentation

- Routine antenatal care
- Intrapartum care of healthy pregnant women
- Monofer infusion for iron deficiency in adults (Standard Operating Procedure)

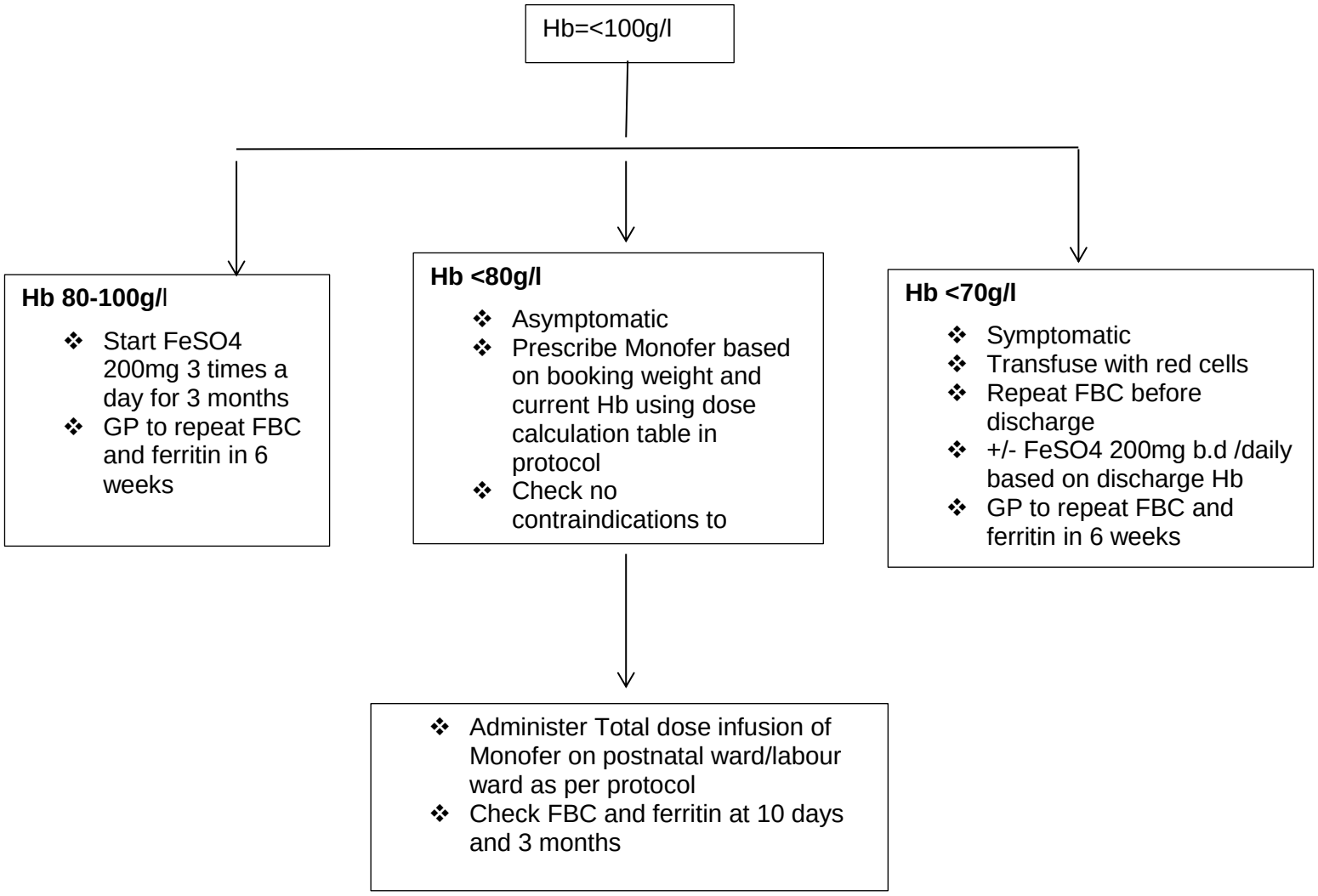
APPENDIX 1: Antenatal Management of Iron Deficiency Anaemia in Pregnancy Algorithm (KEY POINTS)



APPENDIX 2: ANAPHYLAXIS ALGORITHM (Resuscitation Council/ UK)



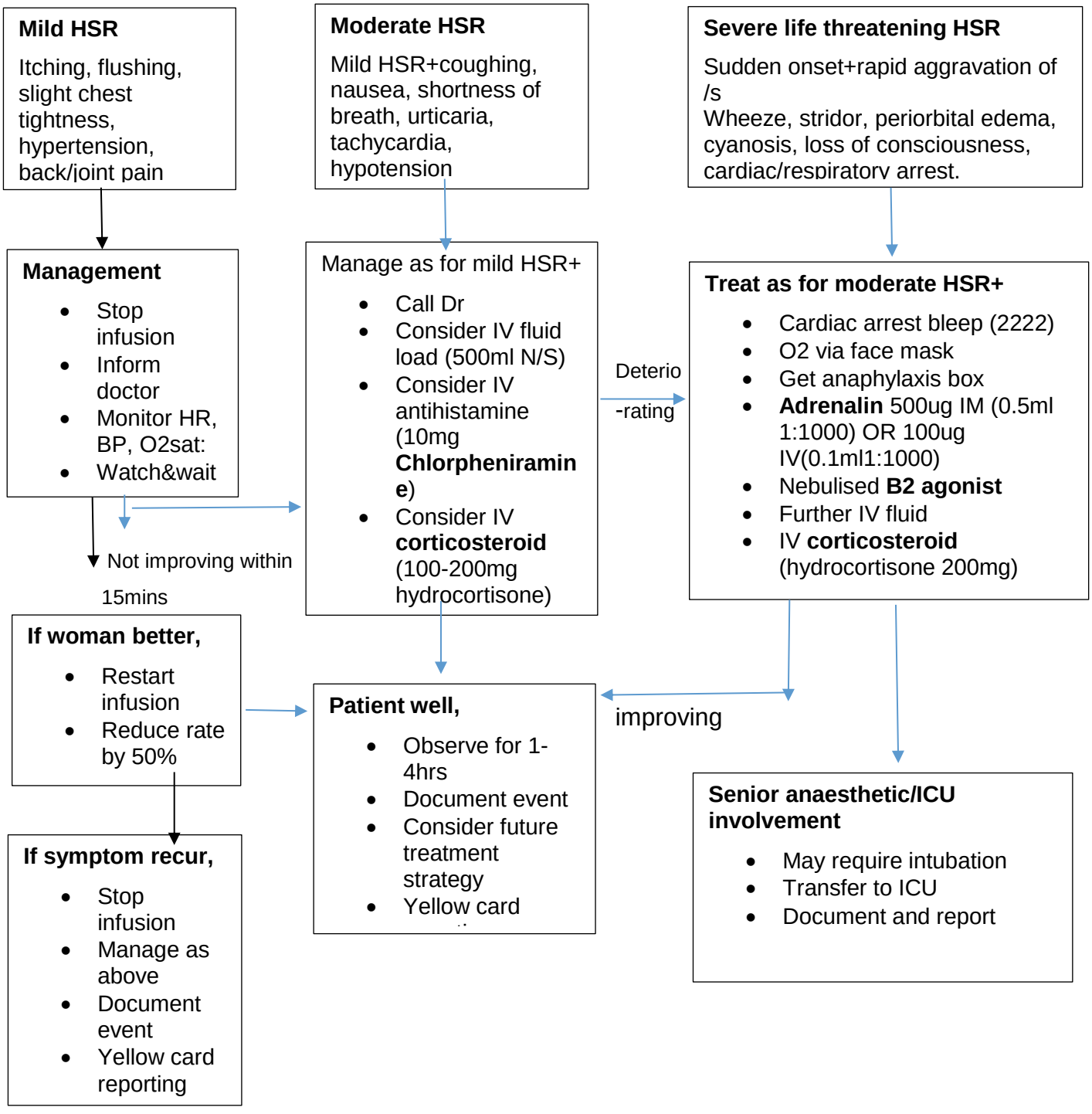
APPENDIX 3: Postnatal Management of Iron Replacement for Blood loss



APPENDIX 4: REACTION MANAGEMENT ALGORITHM

Grading and management of acute hypersensitivity reactions to intravenous iron infusions

If any of the below apply, the woman will be at greater risk of hypersensitivity reactions				
PMH& Allergies	**Liver disease**		**Rheumatoid arthritis or SLE**	
	Asthma		**Previous sensitivity to iron**	
	Eczema		**Other drug allergies**	



APPENDIX 5:

APPENDIX 5: MONOFER DOSING CALCULATION

1. The dose of parenteral iron should be calculated based on **pre-pregnancy weight**, aiming for a target Hb of 110 g/l

2. Total dose required can be calculated from:

A. Ganzoni Equation (If BWt <50 kg)

Total Iron Deficit = Weight {kg} x (Target Hb – Actual Hb) {g/l} x 0.24 + Iron stores {mg}

Iron requirement for iron store; 500 mg if Wt.>35kg
15mg/kg if Wt.<35kg

OR

B. Dosage calculator (Iron in mg) -Target Hb of 110g/l

	Actual Hb Concentration (g/l)					
Body Weight (Kg)	**50**	**60**	**70**	**80**	**90**	**100**
40	**1075**	**975**	**875**	775	675	575
45	**1125**	**1025**	**925**	800	700	600
50	**1200**	**1100**	975	850	725	600
55	**1275**	**1150**	1025	875	750	625
60	**1350**	1200	1075	925	775	625
65	**1425**	1275	1100	950	800	650
70	**1500**	1325	1150	1000	825	650
75	**1575**	1400	1200	1025	850	675
80	**1650**	1450	1250	1075	875	675
85	1700	1500	1300	1100	900	700
90	1775	1550	1350	1125	925	700

•The dose above is expressed as mg of iron

•If the dose that you arrive at is in **red**, then it must be divided for administration because it is above the upper limit of 20mg/kg body weight for total dose infusion. Give half the dose and allow at least one week before giving the other half of the dose.

APPENDIX 6: PRESCRIPTION STICKER

(page 1)

<table>
<tr><td rowspan="4">Pt details
(attach sticker)</td><td colspan="2">PMH (If any of the below apply, the woman will be at greater risk of hypersensitivity reactions)</td><td rowspan="4">BWt at booking

Current Hb (g/l)

Target Hb (110 g/l)

Drug allergies</td></tr>
<tr><td>Liver d/s</td><td>Rheumatoid arthritis /SLE</td></tr>
<tr><td>Asthma</td><td>Previous sensitivity to iron</td></tr>
<tr><td>Eczema</td><td>Acute/Chronic infection</td></tr>
<tr><td colspan="4">Chlorpheniramine 4mg po taken (at least 2 hours pre-infusion)</td></tr>
</table>

Date	Drug	Dose(mg)	Infusion fluid	Route	Duration of infusion	Batch No:	Time given	Given by	Checked by
	Monofer		100ml sodium chloride 0.9%	IV infusion	60 minutes				

Prescriber Print name& signature
Date

(page 2)

A. GANZONI EQUATION (If BWt <50 kg)

Total Iron Deficit (mg) = Weight {kg} x (Target Hb – Actual Hb) {g/l} x 0.24 + Iron stores {mg}

Iron requirement for iron store; 500 mg if Wt.>35kg

15mg/kg if Wt.<35kg

(OR)

B. DOSAGE CALCULATOR (Iron in mg)- Target Hb 110g/l

	Actual Hb Concentration (g/l)					
BWt (Kg)	**50**	**60**	**70**	**80**	**90**	**100**
40	**1075**	**975**	**875**	775	675	575
45	**1125**	**1025**	**925**	800	700	600
50	**1200**	**1100**	975	850	725	600
55	**1275**	**1150**	1025	875	750	625
60	**1350**	1200	1075	925	775	625
65	**1425**	1275	1100	950	800	650
70	**1500**	1325	1150	1000	825	650
75	**1575**	1400	1200	1025	850	675
80	**1650**	1450	1250	1075	875	675
85	1700	1500	1300	1100	900	700
90	1775	1550	1350	1125	925	700

- The dose above is expressed as mg of iron
- If the dose that you arrive at is in **red**, then it must be divided for administration because it is above the upper limit of 20mg/kg body weight for total dose infusion. Give half the dose and allow at least one week before giving the other half of the dose.