

**CLINICAL POLICIES, PROCEDURES & GUIDELINES**

Approved by Quality & Patient Care Committee 21.4.22

**IRON DEFICIENCY – MANAGEMENT IN MATERNITY AND GYNAECOLOGY/ONCOLOGY PATIENTS**

*This LOP is developed to guide clinical practice at the Royal Hospital for Women. Individual patient circumstances may mean that practice diverges from this LOP.*

**1. AIM**

- Replenish iron stores for a woman with iron deficiency anaemia

**2. PATIENT**

- Woman with iron deficiency anaemia

**3. STAFF**

- Medical, nursing and midwifery staff
- Pharmacists

**4. EQUIPMENT**

- Resuscitation equipment
- 20-gauge or smaller intravenous (IV) cannula
- IV starter kit
- Infusion pump
- Infusion set
- Cardiotocograph (CTG)/hand-held Doppler
- Filter needle (for Ferrosig®)
- Light Protective Bag (for Ferrosig®)

**5. CLINICAL PRACTICE**

- Use the following reference ranges to diagnose iron deficiency anaemia<sup>1</sup>:

<b>Pregnant Woman &lt; 20 weeks gestation<sup>1</sup></b>	<b>Pregnant Woman ≥ 20 weeks gestation<sup>1</sup></b>	<b>Postpartum<sup>16</sup></b>	<b>Non-Pregnant Female (Adult)<sup>1</sup></b>
Haemoglobin (Hb) ≤ 110 g/L, and ferritin < 30 µg/L	Hb ≤ 105 g/L, and ferritin < 30 µg/L	Hb < 100 g/L, and/or postpartum haemorrhage (PPH) > 2000 mL	Hb < 120 g/L

- Investigate anaemia in pregnant woman according to Anaemia and Haemoglobinopathies in Pregnancy LOP

**Oral Iron Therapy**

- Administer oral iron as the first line for treatment of iron deficiency anaemia in most circumstances using options of oral iron preparations outlined in Table 1 below

**Table 1: Oral iron preparations<sup>3</sup>**

<b>BRAND NAME</b>	<b>FORMULATION</b>	<b>ELEMENTAL IRON CONTENT PER UNIT</b>	<b>OTHER ACTIVE INGREDIENTS</b>
Ferro-Gradumet®	325 mg ferrous sulfate controlled release tablet	105 mg	Nil
Ferrograd C®	325 mg ferrous sulfate controlled release tablet	105 mg	ascorbic acid 500 mg

Ferro-f-tab®	310mg ferrous fumarate tablet	100 mg	folic acid 350 mcg
Fefol®	270 mg ferrous sulfate controlled release capsule	87.4 mg	folic acid 300 mcg
FGF®	250 mg ferrous sulfate controlled release tablet	80 mg	folic acid 300 mcg
Ferro-tab®	200 mg ferrous fumarate tablet	65.7 mg	Nil
Ferro-Liquid®	30 mg/mL ferrous sulfate oral liquid	6 mg/mL	Nil
Maltofer® syrup	37 mg/mL iron polymaltose complex syrup	10 mg/mL	ethanol 3.25 mg/mL
Maltofer® tablet	370 mg iron polymaltose complex tablet	100 mg	Nil

- Recommend one tablet daily (or 15-30mL of Ferro-liquid®, 10-20mL of Maltofer® syrup) as the starting dose for the above preparations. This can be increased to two tablets taken at the same time if well tolerated.
- Advise woman:
  - *Ferrous salts* are absorbed best if taken on an empty stomach one hour before, or two hours after, food. If it causes stomach upset, it can be taken with, or shortly after food. Avoid taking with tea or coffee
  - *Iron polymaltose* is absorbed best if taken during or immediately after a meal<sup>3</sup>
- Inform woman that commonly reported side effects of oral iron include constipation, black stools, abdominal discomfort, nausea and vomiting<sup>3</sup>
- Give woman patient information leaflet about iron deficiency anaemia (see Appendix 1)

### Parenteral Iron Therapy

- Discourage administration of iron by the intramuscular (IM) route. It is no safer than the IV route. IM iron injections tend to be painful and there is significant risk of permanent skin staining
- Consider IVs iron in the following circumstances:
  - iron deficiency anaemia in a woman unresponsive to, or intolerant/non-compliant with oral iron, or where absorption of oral iron is likely to be impaired, e.g. inflammatory bowel disease, or where there is inadequate time for oral replacement e.g. birth expected within three weeks, and/or severe anaemia - Hb < 80g/L
  - symptomatic blood loss, or at high risk of significant blood loss in the antenatal or postnatal period where iron deficiency is diagnosed, with or without a reduction in Hb (Hb < 100 g/L postnatally)
  - woman at high risk of intrapartum/intraoperative blood loss, where iron deficiency or iron deficiency anaemia is diagnosed, and woman is unable to achieve target ferritin > 100 µg/L with oral supplementation or women is unwilling/unable to accept blood products<sup>2</sup>
- Provide woman with an information leaflet about IV iron (Appendix 2)
- Discuss the procedure with the woman
- Discuss contraindications/cautions with the woman:
  - hypersensitivity to any components contained within iron infusion preparation
  - anaemia not due to iron deficiency (e.g. haemolytic anaemia, vitamin B12 deficiency)<sup>7,8</sup>
  - first trimester of pregnancy – due to risk of hypersensitivity reactions
  - evidence of iron overload or disturbances in utilisation of iron<sup>8</sup>
  - acute or chronic infections, asthma, eczema, or atopic allergies as elemental iron tends to accumulate in inflamed tissues
  - chronic polyarthritis
  - uncontrolled hyperparathyroidism
  - hypophosphataemia
  - hepatic impairment, decompensated hepatic cirrhosis, infectious hepatitis
- Discuss potential adverse reactions with the woman:
  - Fetal bradycardia may occur with parenteral iron preparations.
  - Kounis Syndrome (Acute Coronary Syndrome associated with hypersensitivity reactions) has been reported with parenteral iron preparations (Unknown frequency).

### Iron Polymaltose (Ferrosig®) – see product information for full list

- flushing, sweating, chills, and fever, chest, and back pain
- nausea and vomiting
- headache, dizziness
- hypersensitivity and anaphylactic reactions
- joint and muscle pain, arthralgia, sensation of stiffness of the arms, legs, or face
- faintness, syncope, tachycardia, hypotension, circulatory collapse

- bronchospasm with dyspnoea, cough
- rash, urticaria<sup>2, 11</sup>

**Ferric Carboxymaltose (Ferinject®)– see product information for full list**

- mild headache
- nausea, abdominal pain, rash, constipation, diarrhoea, injection site reaction
- hyperferritinaemia, hypophosphataemia
- skin staining with extravasation<sup>5</sup>
- anaphylaxis (uncommon)
- Obtain verbal consent for procedure and document consent in the medical record (to be completed by Medical Officer).
- Confirm woman's pre-pregnancy weight, or current weight if not pregnant. Document on fluid order chart, eMR or medical records.
- Determine which iron preparation to prescribe (Table 2)

**Table 2: Supply and control of parenteral iron therapy at RHW**

	Inpatients	Upon Discharge	Outpatients
<b>Iron polymaltose (Ferrosig®)</b>	Yes	No	No
<b>Ferric carboxymaltose (Ferinject®)</b>	Yes (restricted)*	No**	No**

\* See SESLHD Quality Use of Medicines (QUM) restrictions

\*\* RHW pharmacy will not supply to outpatients. A prescription for a community pharmacy should be given prior to appointment

- Be aware of the following prescribing and supply restrictions:
  - Prescribe iron polymaltose (Ferrosig®) for woman who is an inpatient unless fluid restriction or rapid correction of iron stores is indicated
  - Inpatient ferric carboxymaltose (Ferinject®) is restricted to:
    - woman where iron polymaltose is inappropriate due to fluid restriction (e.g. congestive cardiac failure)
    - pre-operative woman where rapid repletion is required and/or anticipated postoperative Hb decrease is  $\geq 30$  g/L
    - specific situations where rapid intravenous iron infusion times is essential as recommended by a specialist/consultant (e.g. woman with dementia)
    - woman who does not meet the criteria for ferric carboxymaltose, but has an Individual Patient Usage form (IPU) completed and approved by Drugs and Therapeutics Committee.

CALCULATION METHOD FOR IRON POLYMALTOSE (Ferrosig®)

- Calculate dose of iron required based on weight and haemoglobin using Ganzoni formula or Table 3 and 4: Ganzoni formula<sup>2</sup>

$$\text{Cumulative iron dose (mg)} = \text{weight (kg)} \times (\text{target Hb} - \text{actual Hb g/L}) \times 0.24 + \text{iron stores}$$

- Target Hb = 130g/L for weight < 35kg, and 150g/L for weight  $\geq 35$  kg
- Iron stores = 15 mg/kg for weight < 35 kg, and 500 mg for weight  $\geq 35$  kg
- Round down to the nearest 100mg if weight  $\leq 66$ kg and round up to nearest 100mg if weight > 66kg

**Table 3. Dose of iron polymaltose (as elemental iron) calculated using the Ganzoni formula.**

Total dose must not exceed 2500mg.

Body weight (kg)	Hb (60 g/L)	Hb (75 g/L)	Hb (90 g/L)	Hb (105 g/L)
	Dose (mg)	Dose (mg)	Dose (mg)	Dose (mg)
30	950	850	750	650
35	1250	1150	1000	900
40	1350	1200	1100	950
45	1500	1300	1150	1000
50	1600	1400	1200	1050
55	1700	1500	1300	1100
60	1800	1600	1350	1150
65	1900	1650	1450	1200
70	2000	1750	1500	1250

75	2100	1850	1600	1300
80	2250	1950	1650	1350
85	2350	2050	1700	1400
96	2450	2150	1800	1450

#### CALCULATION METHOD FOR IRON CARBOXYMALTOSE (Ferinject®)

**Table 4. Dose of ferric carboxymaltose (as elemental iron) calculated using the Ganzoni formula**

Haemoglobin (Hb) (g/L)	Cumulative Ferric Carboxymaltose (Ferinject®) Dose	
	Body weight 30- < 70 kg	Body weight ≥ 70 kg
< 100 g/L	1500 mg	2000 mg
≥ 100 g/L	1000 mg	1500 mg

- Note:
  - Limit initial dose to 500mg for a woman with an Hb ≥ 140 g/L.
  - Recheck iron parameters prior to repeat dosing. Do not administer 1000 mg more than once a week for a pregnant woman. It is recommended that the maximum cumulative dose in a pregnant woman is restricted to:
    - 1000 mg with Hb ≥ 90 g/L
    - 1500 mg with Hb < 90 g/L
- Complete [Clinical Pathway Ferric Carboxymaltose \(Ferinject\) Infusion SES060255 form](#) (Appendix 3) if ferric carboxymaltose is prescribed and file in medical record.
- Give woman who has been discharged or who is an outpatient a Pharmaceutical Benefits Scheme (PBS) prescription to obtain iron carboxymaltose from a community pharmacy.
- Book only one infusion per day for outpatients in:
  - Pregnancy Day Stay Unit for public antenatal woman (phone 02 93826417)
  - Antenatal Ward for private antenatal woman (phone 02 93826448)
  - Gynaecology/Oncology Day Stay for gynae/oncology woman or local GP clinic if non-urgent
- Complete [Clinical Pathway Iron Polymaltose Infusion SES060258 form](#) if iron polymaltose is prescribed (Appendix 4) and file in medical record.
- Commence intravenous iron infusion by 1500 hours Monday to Friday, only where direct nursing supervision is available. Adrenaline and emergency trolley must be readily available
- Prescribe iron infusions on the Intravenous Adult Fluid Order Form, by medical officer. The infusion is ordered as elemental iron and should include dosage, diluent, and infusion rate. e.g. **“XXX mg iron (as salt form)” in XXX mL sodium chloride 0.9%.**
  - Inpatient iron infusions will be dispensed and supplied by the RHW pharmacy

#### Dilution and administration

- Administer infusion, through a standard IV line with 200-micron filter
- Check IV cannula for patency by checking for blood return
- Flush IV cannula with 10 mL sodium chloride 0.9% prior to infusion. If there is any pressure, stop immediately. If there are any concerns, re-site cannula
- Immobilise woman's arm and instruct woman to avoid movement of arm to prevent extravasation
- Commence IV infusion via pump as per table 5 for ferric carboxymaltose, and as follows for iron polymaltose:
  - Commence the slow (standard) protocol unless they have received iron polymaltose previously without reaction
  - Stop the infusion if the woman experiences an adverse reaction and immediately advise Medical Officer if CERS is not appropriate. If deemed safe to restart the infusion following medical review, recommence infusion at a slower rate of 60 mL/hr or as instructed by the treating Medical Officer

- Note the rapid protocol should only be used for:
  - Woman receiving subsequent infusions where Ferrosig® has previously been well tolerated
  - Woman who is haemodynamically stable
  - Total dose is ≤ 1500 mg iron (as polymaltose)
  - Woman who does not have a condition that puts them at higher risk of reactions
  - Rapid protocol has not been trialled in patients with class III/IV heart failure, known left ventricular ejection fraction < 30%, known kidney disease with an eGFR < 15 mL/min, or otherwise at risk of fluid overload

**Slow (or Standard) Protocol for iron polymaltose<sup>12</sup>**

- Add total dose of iron (up to 2,500 mg) to 500 mL sodium chloride 0.9%. Iron polymaltose can be given in a smaller volume but the **maximum concentration of iron polymaltose is 5 mg/mL**
- Start the infusion at a rate of 40 mL/hr for 15 minutes, then if vital signs are within normal limits and no adverse reactions are identified, increase the rate to 120 mL/hr

**Rapid Protocol for iron polymaltose<sup>13</sup>**

- Add total dose of iron (up to 1,500 mg) to 250 mL sodium chloride 0.9%
- Start the infusion at a rate of 40 mL/hr for 15 minutes, then if tolerated, increase the rate to 250 mL/hr...

For Iron Carboxymaltose (Ferinject®) dilution use the following table:

**Table 5: Dilution and administration of ferric carboxymaltose (Ferinject®) for IV infusion**

<b>Ferric Carboxymaltose (Ferinject®) Dose</b>	<b>Maximum Volume of Sterile Sodium Chloride 0.9% Solution</b>	<b>Minimum Administration Time</b>
> 200-500mg (>4-10mL)	100 mL	6 minutes
> 500-1000mg (>10-20 mL)	250 mL	15-30 minutes

Note: Do not dilute to concentrations less than 2 mg iron/mL for stability reasons

- Remain with woman at the commencement of the infusion and perform regular observations at baseline and during iron infusion according to type of infusion:
  - Blood pressure
  - Pulse rate
  - Oxygen saturation
  - Respiration rate
  - Temperature
  - Foetal heart monitoring for antenatal woman - intermittent auscultation is adequate if no other risk factors <sup>2</sup>

**Iron Polymaltose (Ferrosig®)**

- Remain with the woman for the first 15 minutes of the infusion
- Perform observations at baseline, 15 minutes after the commencement of the infusion and then hourly for the duration of the infusion.
- Perform observations 60 minutes after completion of the infusion

**Ferric Carboxymaltose (Ferinject®)**

- Perform observations 5 minutes after commencement and at the end of the infusion
- Perform observations 30 minutes after completion of infusion

- Recognise adverse reaction and immediately turn off iron infusion, initiate CERS or CODE BLUE call, and commence resuscitation for anaphylactic reaction. Beware aware that, anaphylactic reactions have been reported in those who have tolerated a previous dose
- Administer promethazine, hydrocortisone and paracetamol as prescribed by the medical officer (MO) for mild reactions
- Perform the following if extravasation is suspected:
  - Immediately stop the infusion
  - Remove cannula
  - Apply ice to cause local vasoconstriction and decrease fluid absorption
  - Do not massage the area
  - Request medical review
  - Document the management including volume of iron infused
- Confirm presence of fetal heart rate on admission and before discharge in a pregnant woman
- Flush IV cannula with 10 mL sodium chloride 0.9% on completion of infusion and remove cannula after final set of observations
- Complete documentation in the medical record

## 6. DOCUMENTATION

- Medical record
- Adult Fluid Order Form
- [Clinical Pathway Ferric Carboxymaltose \(Ferinject®\) Infusion SES060.255](#) Form
- [Clinical Pathway Iron Polymaltose Infusion SES060.258](#) Form

## 7. EDUCATIONAL NOTES

- All staff involved with the prescribing, dispensing and administration must be aware of this LOP to ensure the safe and appropriate use of iron and appropriate management of adverse reactions.
- Definitions
  - **Iron deficiency** – ferritin < 30 µg/L and/or transferrin saturation < 20%<sup>1</sup>
  - **Anaemia** – pregnant woman with Hb ≤ 110 g/L prior to 20 weeks or with Hb ≤ 105 g/L after 20 weeks; non-pregnant woman with Hb ≤ 120 g/L<sup>1</sup>
- Risk factors for iron deficiency anaemia and its consequences in a woman:
  - Aboriginal and Torres Strait Islander, adolescents, recent immigrants
  - A woman with past history of anaemia
  - Multiparity ≥ Para 3, particularly if consecutive pregnancy is < 1 year following previous delivery, or last birth was complicated by PPH
  - Vegetarian, vegan
  - Low socioeconomic status
  - High risk of bleeding, excessive menstrual bleeding, e.g. placenta praevia, major gynaecological surgery
  - A woman who will refuse transfusion or unable to access transfusion, e.g. Jehovah's Witness or red cell antibodies<sup>2</sup>
- Iron deficiency is the leading cause of anaemia during pregnancy. It is associated with increased risk of perinatal morbidity and mortality, low birth weight, preterm birth, transfusion, and maternal morbidity<sup>9,14</sup>
- There is no agreed definition of iron deficiency anaemia in pregnancy. Local policy uses Hb < 110 g/L in a woman less than 20 weeks gestation, and Hb < 105 g/L after 20 weeks gestation
- Iron infusion may be considered in higher Hb and ferritin values to optimise outcomes where oral iron is not suitable. This may include women with known major placenta praevia, who will not/cannot receive blood products or who are expected to have excessive surgical or intrapartum blood loss or where birth is imminent
- IV iron results in more rapid restoration of Hb and iron stores than oral iron, however levels of Hb are equivalent at 3 months<sup>10</sup>
- Iron polymaltose costs \$24 while Ferric carboxymaltose costs \$284. Hence the QUM committee has restricted the use of carboxymaltose to inpatients due to costs in relation to efficacy.

### Adverse reactions

- Literature reports widely varying rates of adverse effects across published studies, however incidence of adverse reactions is lower with iron polymaltose (Ferrosig®) compared with ferric carboxymaltose (Ferinject®)<sup>9</sup>
- Adverse reactions can be delayed by 1 to 2 days after treatment with iron infusions
- Women with the following conditions may be at a higher risk of adverse reactions:
  - Low iron binding capacity
  - Folic acid deficiency
  - History of allergic disorders (including drug allergies)
  - Cardiovascular disease
  - Autoimmune or inflammatory conditions may be at particular risk of delayed reactions, including fever and exacerbation or reactive joint pain<sup>12</sup>
- Infusions must always be administered with ready access to resuscitation equipment
- Caution must be taken where there is suspected acute or chronic infection
- Length of iron infusion administration may be extended if local irritation occurs
- In the case of infiltration/extravasation leading to skin staining, laser therapy has been successful in reducing skin staining long term
- Following iron infusion, changes to iron stores can be noticeable within 1-12 weeks
- Oral supplementation is not usually required after infusion to maintain adequate iron levels. Continuing oral supplementation post infusion ultimately depends on the woman's situation and the clinical judgement of the prescriber. Oral iron supplements should not be used in the first 5 days following ferric carboxymaltose infusion, or in the first 7 days following iron polymaltose infusion, as there will be poor oral absorption.<sup>1</sup>
- Lee and Leung (2017) report on a study of the safety profile of Iron polymaltose. Of 1103 patients who received the infusion 29 had an adverse drug reaction. 28 of the 29 adverse drug reactions occurred within 65 minutes of the commencement of the infusion. The most common reaction was urticaria. Lee and Leung (2017) observed no cases of anaphylaxis however, 4 cases experienced hypotension which responded to fluid resuscitation<sup>12</sup>

## Clinical Pathway Forms

- Clinical Areas should order forms from StreamDirect

## 8 RELATED POLICIES AND PROCEDURES

- Anaemia and Haemoglobinopathies in Pregnancy
- Blood Products – Management of pregnant woman unable to use blood products
- Blood Component Management and Administration, POWH/SSEH CLIN018
- Clinical Emergency Response system (CERS) – Management of the deteriorating patient
- Fetal heart Rate Monitoring – Maternity MoH GL2018/025

## 9 RISK RATING

- High

## 10 NATIONAL STANDARD

- Medication Safety

## 11 REFERENCES

1. Australian Red Cross Blood Service (2018). Toolkit for Maternity Blood Management. Retrieved from: <https://transfusion.com.au/node/2410>
2. The Royal Women's Hospital. Iron Deficiency – Management in Maternity and Gynaecology Patients (2018)
3. AMH (2019). Oral products for treatment of iron deficiency anaemia. Retrieved from: <https://amhonline.amh.net.au.acs.hcn.com.au/chapters/blood-electrolytes/tables/iron-deficiency-anaemia-table>
4. AMH (2019). Iron. Retrieved from: <https://amhonline.amh.net.au.acs.hcn.com.au/chapters/blood-electrolytes/drugs-anaemias/other-drugs-anaemias/iron>
5. Government of Western Australia Department of Health. King Edward Memorial Hospital. Clinical Guidelines Obstetrics and Gynaecology: Management of infiltration/extravasation of intravenous iron therapy (2014). Retrieved from: [http://www.kemh.health.wa.gov.au/development/manuals/O&G\\_guidelines/sectiona/4/a4.13.5.pdf](http://www.kemh.health.wa.gov.au/development/manuals/O&G_guidelines/sectiona/4/a4.13.5.pdf)
6. WHO (2015). The global prevalence of anaemia in 2011. Retrieved from: [https://www.who.int/nutrition/publications/micronutrients/global\\_prevalence\\_anaemia\\_2011/en/](https://www.who.int/nutrition/publications/micronutrients/global_prevalence_anaemia_2011/en/)
7. MIMS Online Australia (2016). Ferrosig® Product Information. Retrieved from: [https://www.mimsonline.com.au.acs.hcn.com.au/Search/FullPI.aspx?ModuleName=ProductInfo&searchKeyword=ferrosig&PreviousPage=~/Search/QuickSearch.aspx&SearchType=&ID=65580001\\_2](https://www.mimsonline.com.au.acs.hcn.com.au/Search/FullPI.aspx?ModuleName=ProductInfo&searchKeyword=ferrosig&PreviousPage=~/Search/QuickSearch.aspx&SearchType=&ID=65580001_2)
8. MIMS Online Australia (2016). Ferinject® Product Information. Retrieved from: [https://www.mimsonline.com.au.acs.hcn.com.au/Search/FullPI.aspx?ModuleName=ProductInfo&searchKeyword=ferinject&PreviousPage=~/Search/QuickSearch.aspx&SearchType=&ID=91220001\\_2#Contraindications8920](https://www.mimsonline.com.au.acs.hcn.com.au/Search/FullPI.aspx?ModuleName=ProductInfo&searchKeyword=ferinject&PreviousPage=~/Search/QuickSearch.aspx&SearchType=&ID=91220001_2#Contraindications8920)
9. Qassim A, Grovell R, Grzeskowiak (2018). Safety and efficacy of intravenous iron polymaltose, iron sucrose and ferric carboxymaltose in pregnancy: A systematic review. Retrieved from: <https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/ajo.12695>
10. Percy L, Mansour D, Fraser I (2017). Iron deficiency and iron deficiency anaemia in women. Retrieved from: <https://www.sciencedirect.com/science/article/pii/S1521693416300840>
11. SGH-TSH CLIN279 MEDICATION - IRON POLYMALTOSE (FERROSIG®) - PRESCRIBING AND ADMINISTRATION. Retrieved from: [http://seslnhweb/SGSHHS/Business\\_Rules/Clinical/Medication/documents/CLIN279\\_SGH\\_Medication\\_iron\\_poly\\_maltose\\_infusion\\_CM.pdf](http://seslnhweb/SGSHHS/Business_Rules/Clinical/Medication/documents/CLIN279_SGH_Medication_iron_poly_maltose_infusion_CM.pdf)
12. Lee, A. Y. S., & Leung, S. H. P. (2019). Safety profile of iron polymaltose infusions. *Hospital Practice*, 47(2), 96-98. doi:10.1080/21548331.2019.1593006
13. Chan, P. T. Y., Corallo, C. E., Dooley, M. J., Poole, S. G., & Gibson, P. R. (2016). Safety of rapid infusion of iron polymaltose: Comparative study in 300 patients. *Journal of Pharmacy Practice and Research*, 46(4), 324-330.
14. Ray JG, Davidson AJF, Berger H, Dayan N, Park AL. Haemoglobin levels in early pregnancy and severe maternal morbidity: population-based cohort study. *BJOG* 2020; <https://doi.org/10.1111/1471-0528.16216>
15. General guide to Iron and Iron Deficiency: Information for Patients, Families and Carers. Released August 2018, © Clinical Excellence Commission, SHPN (CEC) 180017 [http://cec.health.nsw.gov.au/\\_\\_data/assets/pdf\\_file/0018/440442/A-General-Guide-to-Iron-and-Iron-Deficiency.pdf](http://cec.health.nsw.gov.au/__data/assets/pdf_file/0018/440442/A-General-Guide-to-Iron-and-Iron-Deficiency.pdf)
16. Parvord S, Daru J, Prasannan N, Robinson S, Stanworth S, Girling J (2019) UK guidelines on the management of iron deficiency in pregnancy, British Society for Haematology. *BJH* Oct 2019 <https://onlinelibrary.wiley.com/doi/full/10.1111/bjh.16221>

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<b>GOVERNANCE</b>	
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Chairperson, QUM Committee	Wayne Hsueh, Director of Medical Services (DMS)
Process for removal of previous version of Protocol/Guideline	Replaces Ferinject Local Operating Procedure
Endorsed Maternity Services LOPs group	2/6/2020
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## APPENDIX 1.

### PATIENT INFORMATION:

### IRON DEFICIENCY AND IRON DEFICIENCY ANAEMIA

Iron is used by all cells. It is important for our immune system, mental function, muscle strength, and energy. Iron is also used to make red blood cells (haemoglobin or Hb) to carry oxygen around our body. When you have low iron and low haemoglobin, it is called iron deficiency anaemia.

Symptoms of iron deficiency anaemia can include:

- Feeling weak, tired, and lacking energy
- Feeling short of breath, dizzy or an irregular heartbeat
- Not able to exercise as much as usual
- Getting more infections than normal
- Finding it hard to remember things or concentrate
- Feeling irritable

**Iron Deficiency.** Not having enough iron is most common in teenagers, women of childbearing age, pregnant women, vegans and vegetarians and women with heavy periods. It is also found in some people with medical problems.

**Iron Deficiency Anaemia (IDA)** can develop when low iron is not treated. Over time, all the stored iron is used.

Your recent blood test shows that you have anaemia (low haemoglobin, below the recommended level of 110g/L) and/or low stored iron (ferritin) levels.

You should increase your iron levels by both increasing the iron in the food you eat and by taking an iron supplement. This should improve your energy levels and also ensure plentiful iron is available for you (and your baby if you are pregnant).

#### A. Diet:

Iron is best absorbed into the body from food that you eat. Increase your daily intake of food with high iron content:

- **Red meat:** beef, lamb, veal, pork (the best source)
- **Chicken**
- **Fish**, especially oily fish: tuna, trout, salmon
- **Tofu, soybeans, lentils, beans, baked beans**
- **Cereals**, especially wholegrain. Check the label on bread and breakfast cereals, as some are iron-fortified, e.g. Weet-Bix, All-Bran

Other foods also contain iron, but to a lesser extent e.g. eggs, green leafy vegetables (especially spinach), dried fruit and some other fruit and vegetables.

#### B. Iron Supplements

There are many iron supplements available over the counter at any pharmacy. Check for the *Elemental Iron content* – the higher the better. Choose one of the recommended iron supplements listed below. Start with one tablet and increase to two tablets at the same time each day, depending on your iron levels. Speak with your healthcare provider about this.

To help your body absorb the iron efficiently, take the tablet between meals. Avoid consuming coffee, tea, dairy products (milk, yoghurt, cheese) and calcium supplements at the same time. Try

to spread out the calcium and dairy throughout the rest of your day, as it is still very important for you and your baby. Some women who are taking iron supplements may notice that their stool is darker in colour – this is normal. Iron can cause varied gastrointestinal symptoms including nausea (most commonly), abdominal discomfort, constipation and diarrhoea and occasionally trying a different iron preparation may improve the symptoms. You should drink plenty of water (approximately 1.5 Litre per day) and eat foods high in fibre, such as brown grain bread and rice, fruit, and vegetables.

You are recommended continuing your iron treatment for at least one month after your baby is born. If you are not pregnant, ask your doctor as usually 2-3 months treatment is required.

Iron tablets, like all medicines should be kept in a locked cupboard out of reach and sight of children. A small amount can be poisonous, even fatal, in infants and young children.

Certain medications e.g. thyroxine, methyldopa, antacids, and some antibiotics may improve or reduce absorption of oral iron. All medications should be taken at least 2 hours from the iron tablets.

**Please discuss any concerns with your Midwife or Doctor at your next visit**

TABLE 1. OVERVIEW OF ORAL PREPARATIONS OF IRON AVAILABLE IN AUSTRALIA			
Brand name	Formulation/other active ingredients	Elemental iron content	Approximate Cost*
Ferro-tab	Ferrous fumarate immediate release 200 mg	66 mg	\$5 per 30 tablets
Ferro-f-tab	Ferrous fumarate immediate release 310 mg, folic acid 300 mcg	100 mg	\$5 per 30 tablets
Ferro-gradumet	Ferrous sulfate slow release 325 mg	105 mg	\$18 per 30 tablets
Ferro-grad C	Ferrous sulfate slow release 325 mg, ascorbic acid 500 mg	105 mg	\$27 per 30 tablets
Fefol	Ferrous sulfate, slow release 270 mg, folic acid 300 mcg	87 mg	\$10 per 30 tablets
FGF	Ferrous sulfate, slow release 250 mg, folic acid 300 mcg	80 mg	\$16 per 30 tablets
Maltofer tablets	Iron polymaltose 370 mg	100 mg	\$30 per 30 tablets
Ferro-liquid	Ferrous sulfate oral liquid 150 mg/5 mL	6 mg/mL	\$1 per 100 mg (6 cents per mL)
Maltofer syrup	Iron polymaltose oral liquid 185 mg/5 mL	10 mg/mL	\$1.50 per 100 mg (15 cents per mL)
Abbreviation: OTC = over the counter (available without prescription)			
* Estimated costs from online and retail pharmacies in Australia, July 2019.			

Adapted from: Shand A, Austin K, Nassar N, Kidson-Gerber G. Management of anaemia in pregnancy: a review. *Journal of Pharmacy Practice and Research* 2020

\*Some Information from General guide to Iron and Iron Deficiency: Information for Patients, Families and Carers. Released August 2018, © Clinical Excellence Commission, SHPN (CEC) 180017

### Why do I need IV iron?

You have been prescribed intravenous (IV) iron because you have low haemoglobin and iron levels in your body. The most common way to treat low iron levels is to take iron as a tablet or liquid. This works well for most people and is usually tried first. Some people may need iron to be given straight into the body through a vein if they need to increase their iron levels quickly. The iron is given through a needle and dripped ('infused') into your vein. Sometimes two iron infusions are needed to fully top up iron stores. Please tell your doctor if you have an infection, asthma, eczema, allergies, or any liver disorder, have had a reaction to any type of iron injection or infusion in the past, have a history of high iron levels or haemochromatosis.

### Can the infusion have any effects on my baby during pregnancy and breastfeeding?

Harmful effects have not been reported. Iron infusions are not recommended in the first trimester (14 weeks) of pregnancy.

### Can the infusion have any harmful effects on me?

Intravenous iron is only recommended when the benefit is greater than the possible risks. Possible side effects (5:100) include headache, dizziness, high blood pressure, flushing, nausea, and skin reactions around the drip site. These can include pain in the drip site, bruising, and long lasting or permanent **brown staining of the skin** due to accidental leakage of the medicine. Other side effects (less than 1:100) include mild allergic reaction, numbness in the arm, racing heartbeat, low blood pressure, shortness of breath, vomiting, heartburn, stomach pain, constipation, diarrhoea, itchiness, hives, back pain, chest pain, high temperature and rash. A very rare side effect (less than 1:1000) is a **serious allergic reaction** (anaphylactic reaction). In rare cases this can be life threatening. You will be closely monitored while IV iron is given, and for 30 minutes after.

### How is intravenous iron given?

We administer IV iron in a medical setting due to the possible side effects. A full set of your observations will be taken before starting the infusion. If you are pregnant, we will listen to your baby's heartbeat. A cannula (drip) will be inserted into your arm and the infusion commenced. It is critical at this stage that you keep your arm still to prevent the cannula coming out. It is very important that you inform your care provider immediately if you think that the cannula has come out, or you are feeling pain/stinging/burning in your arm.

### Will I have any after effects?

Sometimes women may feel a little tired. This should not prevent you driving home. Some women may have darker urine. Sometimes side effects (e.g. headache, muscle, or joint pain) can start 1 to 2 days later. Mostly they will settle down by themselves over the next couple of days. If they worry you or interfere with your daily activities, contact your doctor or infusion centre for advice. **If you have chest pain, trouble breathing, dizziness or neck / mouth swelling, please seek urgent medical attention/call an ambulance (000).**

**How long will the process take?**

This depends on the type of iron you get. The whole process may take between 1-5 hours and is done during normal business hours.

**How long will it take for my iron levels to improve?**

It will take 2-4 weeks for your haemoglobin levels to improve but may take longer than that to normalise. Your haemoglobin levels will be checked 4-6 weeks after this infusion.

**Should I continue to take iron tablets or liquid?**

Usually this is not needed but please check with your health care provider. It is important that you do not take any iron tablets or liquid for 7 days after the infusion.

Modified from: Intravenous iron infusions, Department for Health & Ageing, Government of South Australia. *BloodSafe TP-L3-415 v1.0 2016. Modified July 2019*



SES060.255

Holes Punched as per AS 2828.1: 2012  
 BINDING MARGIN - NO WRITING

80085 011113



**Health**  
 South Eastern Sydney  
 Local Health District

FAMILY NAME

MRN

GIVEN NAME

MALE  FEMALE

Facility:

D.O.B. \_\_\_\_ / \_\_\_\_ / \_\_\_\_ M.O.

ADDRESS

**CLINICAL PATHWAY  
 FERRIC CARBOXYMALTOSE  
 (Ferinject™) INFUSION**

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

Peer LOS	1-4 hours
Intended users	Patients, nurses, medical officers, allied health
Executive sponsor	Nursing Co-Director – Surgery & Peri Operative Service
Date for review	July 2014

**Use of Clinical Pathways**

- The Clinical Pathway is a guide only.
- The Clinical Pathway is part of the medical record and therefore a legal document.
- Always view each patient as an individual and consider if the intervention is appropriate.
- Do not hesitate to depart from this Clinical Pathway if you consider it is appropriate to do so based on your own clinical judgment and consultation with the doctor.
- The Clinical Pathway is to remain with the patient's observation and medication charts and must accompany the patient to other departments.
- The Clinical Pathway is to be utilised in conjunction with the Doctors' rounds. It does not take the place of a Doctor's order.
- The Clinical Pathway is to be used as the bedside handover tool.

**Guide to Care**

- Affix patient label; insert date (each day/page of the Clinical Pathway).
- As the pathway is multidisciplinary, each discipline initials in the appropriate column after events have actually occurred or each intervention has been achieved.
- So that initials can be recognised staff must also sign, print name and designation in the signature log for each day of the Clinical Pathway.
- Enter N/A if the intervention is not applicable during your shift.
- Enter x to indicate the cue has been read but not performed.
- Enter ✓ to indicate that this task was completed.
- If there is a deviation from the Clinical Pathway, then this is to be documented as a variance in the patient notes. The recording of variances is the responsibility of all health professionals.

**Variance Documentation**

A variance can be in relation to the patient, physician, system or community/family and can be positive or negative. It can therefore be:

- Any event noted on the Clinical Pathway not occurring as outlined on the Pathway.
- Any event not pre-printed on the Clinical Pathway eg. CVC removed due to inflammation.
- Any event that occurs earlier than outlined on the Clinical Pathway.

If a variance occurs, document a 'V' and your initials in the appropriate shift column, then record the variance in the continuation progress notes (SMR050.001)

- Document the date, time and day of stay
- Describe the variance eg. Infection.
- Describe the action, eg. IV removed due to inflammation
- Document the outcome.
- Sign

All charts checked	Name, Designation Print and Sign	Name, Designation Print and Sign
Nurse caring for patient		
Nurse receiving handover		
Nurse giving handover		
Nurse receiving handover		

Contact number of responsible person to collect patient post infusion

NO WRITING

Page 1 of 2

CLINICAL PATHWAY FERRIC CARBOXYMALTOSE  
 (Ferinject™) INFUSION

SES060.255

FAMILY NAME		MRN
GIVEN NAME		<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE
D.O.B. ____/____/____		M.O.
ADDRESS		
LOCATION / WARD		
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE		

**Facility:**

**CLINICAL PATHWAY  
FERRIC CARBOXYMALTOSE  
(Ferinject™) INFUSION**

√ = attended X = not attended N/A = Not applicable  
V = Variance

**Day Prior to Admission** **Initials**

Referral for admission available and current in date	Yes <input type="checkbox"/>	
Medical team to write up medication order	Yes <input type="checkbox"/>	
Medical Team to write up relevant fluid orders	Yes <input type="checkbox"/>	
Medical Record available	Yes <input type="checkbox"/> N/A <input type="checkbox"/>	

**Day of Admission**

Date: \_\_\_\_\_ Time: \_\_\_\_\_

<b>Observations</b>	Baseline observations recorded SEI110.001 Observation Chart	
	BSL _____ if applicable	N/A <input type="checkbox"/>
	Waterlow score _____ if applicable	N/A <input type="checkbox"/>
	Falls risk score _____ if applicable	N/A <input type="checkbox"/>

<b>Medications</b>	All medications documented as necessary before commencement of treatment	Yes <input type="checkbox"/>
	Premedication given	Yes <input type="checkbox"/> N/A <input type="checkbox"/>

<b>Identification</b>	Arm band in situ	Yes <input type="checkbox"/>	Allergies _____
	Consent form checked and signed	Yes <input type="checkbox"/>	

<b>Safety</b>	Adrenaline, antihistamines, corticosteroids and resuscitation equipment should be readily available	Yes <input type="checkbox"/>
	If any signs or symptoms of acute infusion reactions develop, infusion is to be <b>stopped immediately</b> and medical assistance called	
	Must be diluted with sodium chloride 0.9%. Administer by IV infusion not exceeding 0.3 mL of ferric carboxymaltose (15 mg of iron) per kg bodyweight or the calculated cumulative dose up to a maximum dose of 20 mL (1000 mg of Iron). Do not administer more than 20 mL (1000 mg of iron) more than once per week.	

<b>Education</b>	Inform patient of procedure, educate patient on possible side effects	
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<b>IV access</b>	Cannula inserted by Nurse <input type="checkbox"/> Medical Officer <input type="checkbox"/>	
	VIP score _____ on discharge	

<b>Ferric carboxymaltose Infusion Rate Schedule</b>	Ferric carboxymaltose 100 mg to 200 mg (2 mL to 4 mL) in 50 mL sodium chloride 0.9% over 3 minutes	<input type="checkbox"/>
	Ferric carboxymaltose >200 mg to 500 mg (>4 mL to 10 mL) in 100 mL sodium chloride 0.9% over 6 minutes	<input type="checkbox"/>
	Ferric carboxymaltose >500 mg to 1,000 mg (>10 mL to 20 mL) in 250 mL sodium chloride 0.9% over 15 minutes	<input type="checkbox"/>

<b>Observations</b>	Baseline observations recorded pre infusion	Yes <input type="checkbox"/>
	Observations every 15 minutes	Yes <input type="checkbox"/>
	Observations recorded when infusion complete	Yes <input type="checkbox"/>

<b>Patient requirements</b>	Medical Certificate required	Yes <input type="checkbox"/> N/A <input type="checkbox"/>
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<b>Discharge</b>	Check if patient needs to re book, organise same if applicable	
	Ensure RFA is taken to Admissions Office so appointment is entered in system	<input type="checkbox"/>
	RFA then to be stored in the RFA Book at ward clerk desk	<input type="checkbox"/>
	Discharge Time _____	

Holes Punched as per AS2828.1: 2012  
BINDING MARGIN - NO WRITING





<b>Health</b> South Eastern Sydney Local Health District	FAMILY NAME		MRN
	GIVEN NAME		<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE
<b>Facility:</b>	D.O.B. ____/____/____	M.O.	
	ADDRESS		
<b>CLINICAL PATHWAY                  IRON POLYMALTOSE INFUSION</b>			
LOCATION / WARD			
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE			
Peer LOS	1-4 hours		
Intended users	Patients, nurses, medical officers, allied health		
Executive sponsor	Nursing Co-Director – Surgery & Peri Operative Service		
Date for review	July 2014		

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- Enter x to indicate the cue has been read but not performed.
- Enter √ to indicate that this task was completed.
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- Any event that occurs earlier than outlined on the Clinical Pathway.

If a variance occurs, document a 'V' and your initials in the appropriate shift column, then record the variance in the continuation progress notes (SMR050.001)

- Document the date, time and day of stay
- Describe the variance eg. Infection.
- Describe the action, eg. IV removed due to inflammation
- Document the outcome.
- Sign

All charts checked	Name, Designation Print and Sign	Name, Designation Print and Sign
Nurse caring for patient		
Nurse receiving handover		
Nurse giving handover		
Nurse receiving handover		

Contact number of responsible person to collect patient post infusion

30096 01113

CLINICAL PATHWAY IRON POLYMALTOSE INFUSION SES060.258



		FAMILY NAME	MRN
		GIVEN NAME	<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE
Facility:	D.O.B. ____/____/____	M.O.	
<b>CLINICAL PATHWAY IRON POLYMALTOSE INFUSION</b>		ADDRESS	
		LOCATION / WARD	
		COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE	
		√ = attended to X = not attended N/A = Not applicable V = Variance	
		<b>Day Prior to Admission</b>	
		<b>Initials</b>	
		Referral for admission available and current in date Yes <input type="checkbox"/>	
		Medical team to write up medication order Yes <input type="checkbox"/>	
		Medical Team to write up relevant fluid orders Yes <input type="checkbox"/>	
		Medical Record available Yes <input type="checkbox"/> N/A <input type="checkbox"/>	
Date:	<b>Day of Admission</b>		
	Date:	Time:	
Observations	Baseline observations recorded SEI110.001 Observation Chart		
	BSL _____ if applicable	N/A <input type="checkbox"/>	
	Waterlow score _____ if applicable	N/A <input type="checkbox"/>	
	Falls risk score _____ if applicable	N/A <input type="checkbox"/>	
Medications	All medications documented as necessary before commencement of treatment Yes <input type="checkbox"/>		
	Premedication given	Yes <input type="checkbox"/> N/A <input type="checkbox"/>	
Identification	Consent form checked and signed Yes <input type="checkbox"/>		
	Arm band in situ	Yes <input type="checkbox"/>	
	Allergies _____		
Safety	Adrenaline, antihistamines, corticosteroids and resuscitation equipment should be readily available Yes <input type="checkbox"/>		
	If any signs or symptoms of acute infusion reactions develop, infusion is to be <b>stopped immediately</b> and medical assistance called		
	Infuse iron polymaltose using an infusion pump and administer as per infusion schedule over a period of not less than 2 hours		
	Intravenous cannula to remain insitu until just before discharge		
Education	Inform patient of procedure, educate patient on possible side effects		
IV access	Cannula inserted by Nurse <input type="checkbox"/> Medical Officer <input type="checkbox"/>		
	VIP score _____ prior to removal of cannula		
Iron Polymaltose Infusion Rate Schedule	Commenced at 15 mL per hour for the first 30 minutes <input type="checkbox"/>		
	If no reaction occurs, the rate can be increased to maximum rate of 120 mL per hour <input type="checkbox"/>		
	15 minute observations for first half hour are required, thereafter hourly observations to be attended until infusion completed		
Observations	Baseline observations recorded pre infusion Yes <input type="checkbox"/>		
	Observations every 15 minutes for first half hour Yes <input type="checkbox"/>		
	Observations recorded hourly for remaining infusion Yes <input type="checkbox"/>		
Patient requirements	Medical Certificate required Yes <input type="checkbox"/> N/A <input type="checkbox"/>		
Discharge	Check if patient needs to re book, organise same if applicable		
	Ensure RFA is taken to Admissions Office so appointment is entered in system <input type="checkbox"/>		
	RFA then to be stored in the RFA Book at Ward Clerk desk <input type="checkbox"/>		
	Discharge Time _____		

Holes Punched as per AS2828.1: 2012  
BINDING MARGIN - NO WRITING

