

Policy

Clinical Guideline

Iron Infusion

**Policy developed by: SA Maternal & Neonatal Community of Practice
Approved SA Health Safety & Quality Strategic Governance Committee on:
19 April 2016**

Next review due: 19 April 2019

Summary Clinical practice guideline on the parenteral administration of iron in the peripartum period

Keywords Iron deficiency anaemia, haemoglobin, ferritin, iron supplementation, Ganzoni formula, oral iron, intravenous iron, iron polymaltose, ferric carboxymaltose, iron sucrose, clinical guideline

Policy history Is this a new policy? **N**
Does this policy amend or update an existing policy? **Y v5.0**
Does this policy replace an existing policy? **N**
If so, which policies?

Applies to All SA Health Portfolio

Staff impact All Staff, Management, Admin, Students, Volunteers
All Clinical, Medical, Nursing, Allied Health, Emergency, Dental, Mental Health, Pathology

PDS reference CG150

Version control and change history

Version	Date from	Date to	Amendment
1.0	16 Aug 04	08 Jun 06	Original version
2.0	08 Jun 06	20 Oct 09	reviewed
3.0	20 Oct 09	04 Jan 11	reviewed
4.0	04 Jan 11	04 Feb 14	reviewed
5.0	04 Feb 14	19 April 16	Reviewed
6.0	19 April 16	Current	

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Note

This guideline provides advice of a general nature. This statewide guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient's medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes:

- The use of interpreter services where necessary,
- Advising consumers of their choice and ensuring informed consent is obtained,
- Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
- Documenting all care in accordance with mandatory and local requirements

Explanation of the aboriginal artwork:

The aboriginal artwork used symbolises the connection to country and the circle shape shows the strong relationships amongst families and the aboriginal culture. The horse shoe shape design shown in front of the generic statement symbolises a woman and those enclosing a smaller horse shoe shape depicts a pregnant women. The smaller horse shoe shape in this instance represents the unborn child. The artwork shown before the specific statements within the document symbolises a footprint and demonstrates the need to move forward together in unison.



Australian Aboriginal Culture is the oldest living culture in the world yet Aboriginal people continue to experience the poorest health outcomes when compared to non-Aboriginal Australians. In South Australia, Aboriginal women are 2-5 times more likely to die in childbirth and their babies are 2-3 times more likely to be of low birth weight. The accumulative effects of stress, low socio economic status, exposure to violence, historical trauma, culturally unsafe and discriminatory health services and health systems are all major contributors to the disparities in Aboriginal maternal and birthing outcomes. Despite these unacceptable statistics the birth of an Aboriginal baby is a celebration of life and an important cultural event bringing family together in celebration, obligation and responsibility. The diversity between Aboriginal cultures, language and practices differ greatly and so it is imperative that Perinatal services prepare to respectively manage Aboriginal protocol and provide a culturally positive health care experience for Aboriginal people to ensure the best maternal, neonatal and child health outcomes.

Introduction

- > Oral iron supplementation is inexpensive and an effective means of restoring iron balance in the majority of women with iron deficiency and iron deficiency anaemia (IDA) in the peripartum period (for further information see Anaemia in pregnancy in the A to Z index at www.sahealth.sa.gov.au/perinatal)
 - > In iron deficiency anaemia the oral dose of iron should be 100 - 200 mg of elemental iron daily¹
 - > In non-anaemic iron deficiency lower doses of elemental iron (e.g. 20 - 80 mg daily) may be considered, and may be better tolerated than higher doses¹
 - > The response to therapy should be monitored and if inadequate, intravenous iron should be used¹
- > For women with confirmed iron deficiency that fail to respond to, or are intolerant of supplementation, or where rapid restoration of haemoglobin and iron stores is requ

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intravenous iron may be considered from the second trimester and during the postpartum period^{1,2}

- > There is increasing evidence^{1,3,4} that intravenous iron is more effective, provides more rapid correction of haemoglobin and iron stores and is better tolerated than oral iron in treating iron deficiency anaemia during pregnancy
- > The National Patient Blood Management Guidelines - Obstetric and Maternity: Module 5¹ released in 2015 provides recommendations and practice points on the use of intravenous iron in the peripartum setting (See summary in Appendix 1)
- > Intravenous iron has the potential to reduce the use of blood products
- > In some cases, rapid correction of anaemia with red blood cells may be required to restore oxygen carrying capacity (such as in decompensated and/or acutely bleeding patients). Iron therapy should always follow transfusion to replenish deficient iron stores⁵ (for further information see Blood transfusion in the A to Z index at www.sahealth.sa.gov.au/perinatal)
- > The choice of iron infusion will depend on SA Medicines Formulary guidelines, logistics, availability and individual patient factors
- > Brown staining of the skin (potentially permanent) may occur due to leakage of the drug into the tissues around the injection site. Monitor injection site and educate women to immediately report any discomfort, burning, redness or swelling. In case of paravenous leakage STOP infusion immediately⁶. Refer to each product later in this document for information regarding flushing the line

Intravenous iron

- > Intravenous iron treatment circumvents the natural gastrointestinal regulatory mechanisms to deliver non-protein bound iron to the red cells²
- > As free iron may lead to the production of hydroxyl radicals with potential toxicity to tissues, iron deficiency should be confirmed by iron studies (ferritin levels) before intravenous iron is administered²
- > Facilities and staff trained in management of anaphylaxis should be available. IV iron should not be administered to pregnant women outside a hospital setting
- > When IV iron is prescribed, calculation of the dose should take into consideration the iron deficit (practice point)¹
- > The routine use of IM iron is not advised where alternatives are available (practice point)¹
- > Iron polymaltose (Ferrum H[®] or Ferrosig[®]), iron sucrose (Venofer[®]), and ferric carboxymaltose (Ferinject[®]) are the parenteral iron formulations currently available in Australia
- > A "total-dose" infusion (where iron stores can be repleted in a single treatment episode) can be administered with iron polymaltose (Ferrum H[®] or Ferrosig[®]). In women with mild iron deficiency anaemia, a single dose of ferric carboxymaltose (Ferinject[®]) may be sufficient to fully replete iron stores but 2 doses (at least a week apart) are required in more severe anaemia (see administration and dosing tables below). Iron sucrose (Venofer[®]) can only be given as multiple small intermittent doses over days to weeks not as a large or 'total dose' infusion

Indications

- > Oral iron (in therapeutic doses) is first line therapy for the majority of maternity patients with iron deficiency or iron deficiency anaemia. The response to therapy should be monitored and if inadequate, intravenous iron should be used (practice point)¹
- > In maternity patients with iron deficiency anaemia, intravenous iron is preferred when rapid restoration of haemoglobin and iron stores is required, because it leads to a more rapid increase in these values than other routes of administration (Grade C recommendation)¹
- > In maternity patients requiring iron, intravenous iron is preferred when oral iron is poorly tolerated (affecting compliance), or absorption is likely to be impaired (practice point)¹

Contraindications

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- > First trimester of pregnancy
- > Known hypersensitivity to intravenous or intramuscular iron (discuss choice of intravenous iron preparation and indication with an expert such as haematologist, perinatal physician, nephrologist, or other specialist)
- > Haemochromatosis or anaemia that is not due to iron deficiency or associated with low iron stores (seek advice if cause of anaemia is unclear)
 - > Cases of women with asymptomatic thalassaemia minor (normal or mildly reduced haemoglobin level) and coexisting iron deficiency with indications for intravenous iron may rarely occur (see 'Indications' for intravenous iron above). Intravenous iron is not contraindicated so long as the presence of iron deficiency is confirmed by a low serum ferritin level. If in doubt seek specialist advice
 - > Women with thalassaemia / haemoglobinopathy requiring regular or intermittent blood transfusions (e.g. thalassaemia major or intermedia) may have or be at future risk of iron overload. They should not receive intravenous iron unless recommended by a haematologist (after assessment of the phenotype of their disease and current iron stores)
- > Active systemic infection/bacteraemia

Precautions

- > Significant hepatic dysfunction (discuss risks / benefits with gastroenterologist), avoid in women with hepatic dysfunction where iron overload is a precipitating factor, in particular porphyria cutanea tarda
- > Use with caution in acute or chronic infection after assessing risks / benefits and seek expert advice. Avoid during active systemic infection / bacteraemia
- > Use with caution in asthma, eczema, or other atopic allergies

⚠ WARNING Intravenous iron can cause hypersensitivity reactions (including anaphylactoid), which may be fatal and can occur after previous uneventful doses. Cardiopulmonary resuscitation facilities MUST be available. Stop immediately if signs of allergy or intolerance. Observe for at least 30 minutes post infusion

Calculation of total body iron deficit

- > **⚠ WARNING** This section is for calculation of the woman's total body iron deficit (cumulative amount of iron required to replete body iron stores) NOT the allowable iron dose per infusion which is DIFFERENT for each product. Refer to the specific product information and administration guidelines for information on the maximum iron dose per infusion for each product
- > Calculation of total body iron deficit is based on body weight and haemoglobin as per product information or calculated by the Ganzoni formula below. Seek expert advice if in doubt
- > The total body iron deficit is expressed as milligrams of **elemental iron**

Ganzoni formula:

- > Total body iron deficit (mg) =

$$\text{body weight (kg)}^* \times (\text{target Hb} - \text{actual Hb in g/L}) \times 0.24^{**} + \text{iron depot (mg)}^{***}$$

*Use ideal body weight (non-pregnant) in overweight women. If underweight, use actual body weight (see ideal body weight calculator in Australian Medicines Handbook)

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> **The factor 0.24= 0.0034 x 0.07 x 1,000

For this calculation the iron content of haemoglobin = 0.34%, blood volume = 7% of the bodyweight and 1,000 is the conversion from g to mg

> ***Iron depot:

15 mg/kg for body weight less than 35 kg

500 mg for those with a body weight greater than or equal to 35 kg

Simplified Method for estimating the total body iron deficit (for adult patients of body weight \geq 35 kg). The following table can be used instead of the above calculation:

Estimated total body iron deficit¹⁷

Hb g/L	Body weight* 35 kg to <70 kg	Body weight* \geq 70 kg
#Hb <100 g/L	1,500 mg	2,000 mg
+Hb \geq 100 g/L	1,000 mg	1,500 mg

If Hb is <70 g/L calculate the total body iron deficit more precisely using Ganzoni formula in the product information

+ If Hb is within the normal range for pregnancy then 500 mg (replacement of iron stores) may be sufficient or use Ganzoni formula in the product information to calculate the iron deficit more precisely.

* Use ideal body weight (non-pregnant) in overweight patients (see ideal body weight calculator in Australian Medicines Handbook). If underweight, use actual body weight

Refer to the specific version of this table contained under each product when calculating the iron deficit

Administration

- > **⚠ WARNING** Infusion rates, maximum dose per infusion and dilution are NOT interchangeable between IV iron products. Refer to the specific product information and administration guidelines below
- > All iron preparations can **only** be mixed with 0.9 % sodium chloride
- > Use a dedicated intravenous line and do not add any other medications
- > Administer through infusion pump
- > Anaphylactoid reactions occur most frequently within the first several minutes of administration and are generally characterised by sudden onset of respiratory difficulties, tachycardia and hypotension
- > Adrenaline, oxygen and steroids should be available for immediate use during administration to treat possible anaphylactic reaction For further information see 'Maternal anaphylaxis' in the A to Z index at www.sahealth.sa.gov.au/perinatal
- > Oral iron is not required after IV iron is given if the total iron deficit has been (or will be) repleted with IV iron therapy
- > **Women with systemic allergy to iron polymaltose** (Ferrum H[®], Ferrosig[®]) must not receive ferric carboxymaltose (Ferinject[®]) as cross reactivity may be possible - consult an expert regarding the use of iron sucrose (Venofer[®])
- > **NB:** Brown staining of the skin (potentially permanent) may occur due to leakage of the drug into the tissues around the injection site. Monitor injection site and educate women to immediately report any discomfort, burning, redness or swelling. **In case of paravenous leakage STOP infusion immediately.** Minimise the risk of injection site leakage by flushing with sodium chloride 0.9% before and after administration
- > **NB:** Test doses are no longer recommended at the beginning of an iron infusion as: no evidence of any protective effect¹⁵. However, caution should be taken with each

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Iron infusion

even if previous infusions have been well tolerated. Monitor for signs of hypersensitivity during infusion, and for at least 30 minutes after completion of the infusion

Ferric carboxymaltose¹⁶

> Check the approved indications for using this product within your health service

Ferric carboxymaltose (Ferinject®)			
<p>> ⚠ WARNING DO NOT use this guideline for iron polymaltose (Ferrum H®, Ferrosig®), iron sucrose (Venofer®) or ANY OTHER intravenous iron product as infusion rates and maximum dose per infusion are NOT interchangeable</p> <p>> Women with systemic allergy to iron polymaltose (Ferrum H®, Ferrosig®) must not receive ferric carboxymaltose (Ferinject®) as cross reactivity may be possible - consult an expert regarding the use of iron sucrose (Venofer®)</p>			
Presentation	<p>> 50 mg per mL (2 mL and 10 mL vials)</p> <p>> NB: A Pharmaceutical Benefits Scheme (PBS) prescription should be completed for outpatients, as the 500 mg / 10 mL vials are listed on the PBS (IDA where oral treatment is ineffective or cannot be used)</p>		
Route	<p>> Intravenous infusion</p>		
Dosage	<p>> Calculation of total body iron deficit is based on body weight and haemoglobin. This has been simplified in the table below.</p> <p>> The treating doctor should prescribe the required dose and document verbal consent for the procedure in the case notes</p> <p>> Maximum single dose of 1,000 mg or 20 mg/kg, whichever is less</p> <p>> A second dose at least a week later to make up the remainder of the calculated total body iron deficit may be required (not exceeding 20 mg/kg up to 1,000 mg per infusion)</p> <p>> Dose should be prescribed as milligrams of elemental iron</p>		
ADULT DOSING TABLE:			
Total body iron deficit & dosage per infusion of ferric carboxymaltose (Ferinject®)			
Hb (g/L)	*Body weight 35 to <50 kg	*Body weight 50 to <70 kg	*Body weight ≥70 kg
#Hb <100g/L	Total iron deficit: 1,400 mg 1 st dose: 700 mg [§] 2 nd dose: 700 mg [§]	Total iron deficit: 1,500 mg 1 st dose: 1,000 mg 2 nd dose: 500 mg [^]	Total iron deficit: 2,000 mg 1st dose: 1,000 mg 2nd dose: 1,000 mg
*Hb ≥100g/L	Total iron deficit: 1,000 mg 1st dose: 500 mg 2 nd dose: 500 mg	Total iron deficit: 1,000 mg 1st dose: 1,000 mg 2 nd dose: not required	Total iron deficit: 1,500 mg 1st dose: 1,000 mg 2nd dose: 500 mg [^]
<p>+ If Hb is within the normal range give only the first dose from the Hb ≥100 g/L section of the table above</p> <p># If Hb is <70 g/L calculate the total body iron deficit more precisely using Ganzoni formula in the product information. The first dose can be guided by the Hb <100 g/L section of the table above</p> <p>^ In patients with ongoing blood loss or impending delivery / surgery associated with substantial expected blood loss, consider giving 1,000 mg for 2nd dose</p> <p>§ Where dose is >500 mg and <1,000 mg use 500 mg vial (PBS listed) and discard excess</p> <p>* Use ideal body weight (non-pregnant) in overweight patients (see ideal body weight calculator in Australian Medicines Handbook). If underweight, use actual body weight</p>			

Infusion set up	<p>> Add the calculated dose to sodium chloride 0.9% as per instructions below</p> <p>> To ensure stability of infusion, do not dilute the required dose t</p>
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Iron infusion

	<p>concentration less than 2 mg/mL (with sodium chloride 0.9%)</p> <p>> After dilution, infuse immediately using a volumetric infusion pump</p>
Administration	<p>> NB: Brown staining of the skin (potentially permanent) may occur due to leakage of the drug into the tissues around the injection site. Monitor injection site and educate women to immediately report any discomfort, burning, redness or swelling. In case of paravenous leakage STOP infusion immediately</p> <p>> Add the prescribed dose to 100 mL sodium chloride 0.9% and infuse over a minimum of 15 minutes</p> <p>> On completion, infuse 50 mL sodium chloride 0.9% to ensure the drug is flushed completely</p>
Observations	<p>> Check for any pre-existing skin rashes</p> <p>> Monitor vital signs before the infusion, 5 minutes after commencing the infusion and on completion of the infusion</p> <p>> Check if patient is symptomatic (i.e. ensure patient does not feel faint upon mobilisation)</p> <p>> Patient should be observed for at least 30 minutes following each infusion</p> <p>> Antenatal: confirm presence of fetal heart rate on admission and before discharge</p>
Side effects	<p>Anaphylactoid reactions (rare): ($\geq 1/10,000$, $< 1/1,000$)</p> <p>Hypersensitivity:(uncommon): ($\geq 1/1,000$, $< 1/100$)</p> <p>Other side effects</p> <ul style="list-style-type: none"> > Headache > Dizziness > Nausea > Abdominal pain > Constipation > Diarrhoea > Rash > Injection site reactions > Low blood phosphate levels

Iron polymaltose complex^{11,12,13}

Iron polymaltose complex (Ferrum H [®] or Ferrosig [®])											
<p>> ⚠ WARNING DO NOT use this guideline for iron sucrose (Venofer[®]), ferric carboxymaltose (Ferinject[®]) or ANY OTHER intravenous iron product as infusion rates and maximum dose per infusion are NOT interchangeable</p>											
Presentation	> 50 mg per mL, (2 mL ampoule)										
Route	> Intravenous infusion										
Dosage	<p>> Calculation of the total body iron deficit is determined by body weight and haemoglobin according to the Ganzoni formula or using the nomogram in the product information or alternatively the simplified table below</p> <p>> <u>Simplified Method</u> for estimating the total body iron deficit (for women of body weight ≥ 35 kg)</p> <p>Estimated total body iron deficit¹⁷</p> <table border="1"> <thead> <tr> <th>Hb g/L</th> <th>*Body weight 35 kg to <70 kg</th> <th>*Body weight ≥70 kg</th> </tr> </thead> <tbody> <tr> <td>#Hb <100 g/L</td> <td>1,500 mg</td> <td>2,000 mg</td> </tr> <tr> <td>+Hb ≥100 g/L</td> <td>1,000 mg</td> <td>1,500 mg</td> </tr> </tbody> </table> <p># If Hb is <70 g/L calculate the total body iron deficit more precisely using Ganzoni formula in the product information</p> <p>+ If Hb is within the normal range for pregnancy then 500 mg (replacement of iron stores) may be sufficient or use Ganzoni formula in the product information to calculate the iron deficit more precisely</p> <p>Use ideal body weight (non-pregnant) in overweight women. If underweight, use actual body weight (see ideal body weight calculator in Australian Medicines Handbook)</p> <p>> The treating doctor should prescribe the required dose and document verbal consent for the procedure in the case notes</p> <p>> The total calculated body iron deficit (up to 2,500 mg) may be given in a single infusion</p> <p>> Dose should be prescribed as milligrams of elemental iron</p>		Hb g/L	*Body weight 35 kg to <70 kg	*Body weight ≥70 kg	#Hb <100 g/L	1,500 mg	2,000 mg	+Hb ≥100 g/L	1,000 mg	1,500 mg
Hb g/L	*Body weight 35 kg to <70 kg	*Body weight ≥70 kg									
#Hb <100 g/L	1,500 mg	2,000 mg									
+Hb ≥100 g/L	1,000 mg	1,500 mg									
Infusion set up	<p>> Draw up iron using a filtered needle (e.g. 18 gauge BD blunt filter needle 5 microns). Change to a suitable needle (e.g. 21 gauge BD precision glide needle) before adding the calculated dose to 500 mL of sodium chloride 0.9 % (up to 2,500 mg may be given in 500 mL)</p> <p>> After dilution infuse immediately using a volumetric infusion pump (if prepared by pharmacy, check expiry date and time is not exceeded)</p>										

Iron infusion

Administration	<ul style="list-style-type: none"> > The first 50 mL should be given slowly at 20 to 40 mL per hour > If well tolerated after 50 mL, the rate may be increased to 120 mL per hour, until completion^{10*} > NB: Brown staining of the skin (potentially permanent) may occur due to leakage of the drug into the tissues around the injection site. Monitor injection site and educate women to immediately report any discomfort, burning, redness or swelling. In case of paravenous leakage STOP infusion immediately > On completion, infuse 50 mL sodium chloride 0.9% to ensure the drug is flushed completely⁶
Observations	<ul style="list-style-type: none"> > Check for existing skin rashes before administration > Monitor vital signs before the infusion, at 5 minutes, then every 15 minutes for the first two hours. Continue monitoring hourly until 30 minutes after the completion of the infusion > Antenatal: confirm presence of fetal heart rate on admission and before discharge
Side effects	<ul style="list-style-type: none"> > Anaphylactoid reactions (uncommon): 1:100 to 1:1,000 Other side effects > Headache > Nausea > Joint pain > Tachycardia > Flushing, sweating > Chest and back pain > Urticaria > Bronchospasm with dyspnoea > Hypotension, dizziness > Low blood phosphate levels

NB: *AIDH¹¹ outlines information on more rapid infusions of iron polymaltose. Given the limited available safety data on accelerated infusion rates, these are not considered suitable for this patient population and the standard rates outlined above are recommended

Iron sucrose⁹

- > Check the approved indications for using this product within your health service

Iron sucrose (Venofer[®])										
<ul style="list-style-type: none"> > ⚠ WARNING DO NOT use this guideline for iron polymaltose (Ferrum H[®], Ferrosig[®]), ferric carboxymaltose (Ferinject[®]) or ANY OTHER intravenous iron product as infusion rates and maximum dose per infusion are NOT interchangeable 										
Presentation	> 20 mg per mL (5 mL vial)									
Route	> Intravenous infusion									
Dosage	<p>> Calculation of total cumulative iron sucrose dose, equivalent to the total iron deficit (mg), is determined by the body weight and haemoglobin according to the Ganzoni formula OR using the nomogram in the product information, OR alternatively, use the following simplified method:</p> <p><u>Simplified Method</u> for estimating the total body iron deficit (for women of body weight ≥ 35 kg)</p> <p>Estimated total body iron deficit¹⁷</p> <table border="1"> <thead> <tr> <th>Hb g/L</th> <th>Body weight 35 kg to <70 kg</th> <th>Body weight ≥70 kg</th> </tr> </thead> <tbody> <tr> <td>#Hb <100 g/L</td> <td>1,500 mg</td> <td>2,000 mg</td> </tr> <tr> <td>*Hb ≥100 g/L</td> <td>1,000 mg</td> <td>1,500 mg</td> </tr> </tbody> </table> <p>The estimated total body iron deficit can be rounded up or down to the nearest 200 mg because it is commonly given as separate 200 mg doses (no more than 3 times per week - see below)</p> <p># If Hb is <70 g/L calculate the total body iron deficit more precisely using Ganzoni formula in the product information.</p> <p>+ If Hb is within the normal range for pregnancy then 500 mg (replacement of iron stores) may be sufficient or use Ganzoni formula in the product information to calculate the iron deficit more precisely. *Use ideal body weight (non-pregnant) in overweight women (see ideal body weight calculator in Australian Medicines Handbook). If underweight, use actual body weight</p> <ul style="list-style-type: none"> > ⚠ WARNING Iron sucrose can only be given as small doses (maximum 500 mg per infusion) so multiple intermittent doses are required to cumulatively replace the total body iron deficit > The treating doctor should prescribe the required dose and document verbal consent for the procedure in the case notes > Maximum infusion dose per day, given not more than once per week: <ul style="list-style-type: none"> o Women above 70 kg: 500 mg iron sucrose o Women ≤ 70 kg: Calculate maximum dose according to body weight i.e. 7 mg iron sucrose per kilogram of body weight > Iron sucrose doses of 200 mg should be given no more than 3 times per week > Doses must be expressed as milligrams of elemental iron <p>For more information see: http://www.medsafe.govt.nz/profs/datasheet/v/venoferi</p>	Hb g/L	Body weight 35 kg to <70 kg	Body weight ≥70 kg	#Hb <100 g/L	1,500 mg	2,000 mg	*Hb ≥100 g/L	1,000 mg	1,500 mg
Hb g/L	Body weight 35 kg to <70 kg	Body weight ≥70 kg								
#Hb <100 g/L	1,500 mg	2,000 mg								
*Hb ≥100 g/L	1,000 mg	1,500 mg								



Infusion set up	<ul style="list-style-type: none"> > For stability reasons, dilutions lower than 1 mg/mL Venofer[®] concentration are not permissible > After dilution, infuse immediately using a volumetric infusion pump
Administration	<ul style="list-style-type: none"> > NB: Brown staining of the skin (potentially permanent) may occur due to leakage of the drug into the tissues around the injection site. Monitor injection site and educate women to immediately report any discomfort, burning, redness or swelling. In case of paravenous leakage STOP infusion immediately > If this occurs ice may be applied to cause local vasoconstriction and decrease fluid absorption; avoid massage to the area > 200 mg: Infuse 200 mg iron sucrose (10 mL Venofer[®]) in 100 mL sodium chloride 0.9% over at least 30 minutes > 300 mg: Infuse 300 mg iron sucrose (15 mL Venofer[®]) in 100 mL sodium chloride 0.9% over at least 1.5 hours > 400 mg: Infuse 400 mg iron sucrose (20 mL Venofer[®]) in 100 mL sodium chloride 0.9% over at least 2.5 hours > 500 mg: Infuse 500 mg iron sucrose (25 mL Venofer[®]) in 500 mL sodium chloride 0.9% over at least 3.5 hours > On completion, infuse 50 mL of sodium chloride 0.9% to ensure the drug is flushed completely > ⚠ WARNING Rapid infusion of the maximum iron sucrose dose (500 mg) can lead to severe hypotension
Observations	<ul style="list-style-type: none"> > Check for existing skin rashes before administration > Monitor vital signs before the infusion, then every 5 minutes for 15 minutes, then 30 minutely until / and on completion > Patients should be observed for adverse effects for at least 30 minutes after completion of the infusion > Antenatal: confirm presence of fetal heart rate on admission and before discharge
Side effects	<ul style="list-style-type: none"> > Anaphylactoid (rare): ($\geq 1/10,000$, $< 1/1,000$) Other side effects > Metallic taste > Nausea > Fever > Shivering > Hypotension > Low blood phosphate levels

NB: The Australian Product Information (March 2015) indications are for patients undergoing chronic haemodialysis receiving 100 mg doses only. The NZ Medsafe Venofer[®] Data Sheet with information regarding other doses is more relevant in this population. For further information see URL: <http://www.medsafe.govt.nz/profs/datasheet/v/venoferinf.pdf>

Adverse reaction

- > Stop the infusion
- > Notify medical officer to review as soon as possible
- > Lie the woman flat (If uterine size is greater than 20 weeks of gestation avoid aortocaval compression by using a left lateral wedge / tilt)
- > Oxygen at > 6 L / minute (preferably 12-15 L / minute via non-rebreathing mask)
- > If anaphylaxis is suspected, follow care as per maternal anaphylaxis guideline in the index at www.sahealth.sa.gov.au/perinatal

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- > For nonspecific and minor side effects, close observation using the 'Rapid Deterioration and Response' (RDR) chart with frequent observations including pulse oximetry, blood pressure and respirations until symptoms resolve (at least 1 hour). Appropriate medical review as identified by RDR criteria. Do not recommence infusion
- > Adverse reaction reporting for anaphylaxis:
 - > Document adverse reaction in patients' medical records
 - > Report to the SA Health Safety Learning System (SLS)
 - > Reporting adverse event via Advisory Committee on the Safety of Medicines (ACSOM) where appropriate. Further information available at URL: <https://www.tga.gov.au/reporting-medicine-and-vaccine-adverse-events#who>

Discharge planning

- > Discharge after medical review
- > Advise the woman that delayed systemic reactions may include:
 - > dizziness, syncope
 - > sensation of stiffness in arms, legs or face
 - > chest and back pain
 - > arthralgia, chills, fever, rash
 - > urticaria, angioneurotic oedema
 - > generalised lymphadenopathy
- > Ensure the woman has been given the appropriate patient information including when / how to seek medical attention / advice if required as per the patient leaflet 'Intravenous (IV) iron infusions' which is available in multiple languages at URL: <http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+programs/blood+products+and+programs/bloodsafe/bloodsafe+informatii+n+for+consumers/iron+therapy>

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Useful patient information

- > Patient information on intravenous iron infusions translated into other languages can be found on the BloodSafe website at URL: <http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+programs/blood+products+and+programs/bloodsafe/bloodsafe+information+for+consumers/iron+therapy>

Appendix 1: Patient Blood Management Guidelines: Module 5 Obstetrics and Maternity (as related to the use of iron)¹

Available at URL: <http://www.blood.gov.au/pbm-module-5>

Identifier and grade	Guidance – recommendations, practice points and expert opinion points
R1 GRADE C	The routine administration of iron supplementation to all pregnant women is not recommended. ^a ^a In accordance with Clinical practice guidelines: Antenatal care – Module 1 ¹⁸
R2 GRADE C	The administration of iron to pregnant women with iron deficiency anaemia is recommended; IV iron is preferred when rapid restoration of Hb and iron stores is required.
R3 GRADE C	In maternity patients who require iron therapy for the treatment of anaemia, the routine addition of folic acid is not recommended. ^a ^a Folic acid should be administered for the prevention of neural tube defects, in accordance with Clinical practice guidelines: Antenatal care – Module 1 ¹⁸
PP9	In maternity patients with iron deficiency anaemia, a therapeutic dose of elemental iron (100–200 mg daily) should be prescribed, and the response to therapy monitored. If the response to oral iron is inadequate, IV iron should be used.
PP10	In maternity patients with iron deficiency without anaemia, a low dose of elemental iron (e.g. 20–80 mg daily) may be considered, and may be better tolerated than higher doses.
PP11	In maternity patients requiring iron, IV iron is preferred when oral iron is poorly tolerated (affecting compliance), or absorption is likely to be impaired.
PP12	When IV iron is prescribed, calculation of the dose should take into consideration the iron deficit.
PP13	The routine use of IM iron is not advised where alternatives are available.
PP14	In maternity patients with anaemia, where an ESA is used, it should be combined with iron therapy. ^a ^a ESAs are currently registered with the TGA for anaemia therapy in patients with chronic renal disease, non-myeloid malignancies and those scheduled for elective surgery with an expected moderate blood loss.
EOP1	In women at high risk of anaemia, ferritin should be tested along with complete blood examination early in pregnancy to assess iron stores and anaemia. Other factors contributing to anaemia, such as deficiencies in folic acid and vitamin B12, or hookworm, should be screened for in selected women.
PP5	In maternity patients who are not actively bleeding, non-transfusion therapies, including iron, should be considered as part of the treatment of anaemia. (See recommendations R2 and R3, and practice points PP9–PP14)

R recommendation

PP practice point

EOP expert opinion point

Abbreviations

AIDH	Australian Injectable Drugs Handbook
EMA	European Medicines Agency
e.g.	For example
g	Gram(s)
>	Greater than
≥	Greater than or equal to
Hb	Haemoglobin
IDA	Iron deficiency anaemia
kg	Kilogram(s)
<	Less than
≤	Less than or equal to
L	Litre(s)
mg	Milligram(s)
mL	Millilitre(s)
NB	Note
%	Percent
®	Registered trademark

Version control and change history

PDS reference: OCE use only

Version	Date from	Date to	Amendment
1.0	16 Aug 04	08 Jun 06	Original version
2.0	08 Jun 06	20 Oct 09	reviewed
3.0	20 Oct 09	04 Jan 11	reviewed
4.0	04 Jan 11	04 Feb 14	reviewed
5.0	04 Feb 14	19 April 2016	Reviewed
6.0	19 April 2016	Current	