Hinchingbrooke Health Care NHS
NHS Trust

Protocol for the use of Intravenous Iron Sucrose (Venofer®)

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Approval and Authorisation

Completion of the following signature blocks signifies the review and approval of this Process

Initial approval or Revision	Committee or Team	Date
Initial approval version 1.0	Drug & Therapeutics Committee	23 January 2008

Change History

Version	Date	Author	Reason for change and Sections Affected
Next Review Date			

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Any other printed copies must be checked as to accuracy, currency and version number against the intranet version to ensure that the latest issue is being referred to.

Contents

1 General information

1.1 Investigations required

Patients with anaemia should be fully investigated as appropriate.

The following blood investigations are required prior to starting treatment with IV iron:

- Full blood count + film
- Reticulocyte count
- Iron profile
- CRP

In addition B12 and folate may be indicated.

1.2 Clinical indications

Intravenous iron is indicated for the treatment of iron deficiency in the following situations;

- Demonstrated intolerance to oral iron preparations
- A clinical need to deliver iron rapidly to replenish iron stores
- Active inflammatory bowel disease where oral iron preparations not tolerated or contraindicated
- Patient non-compliance with oral iron therapy

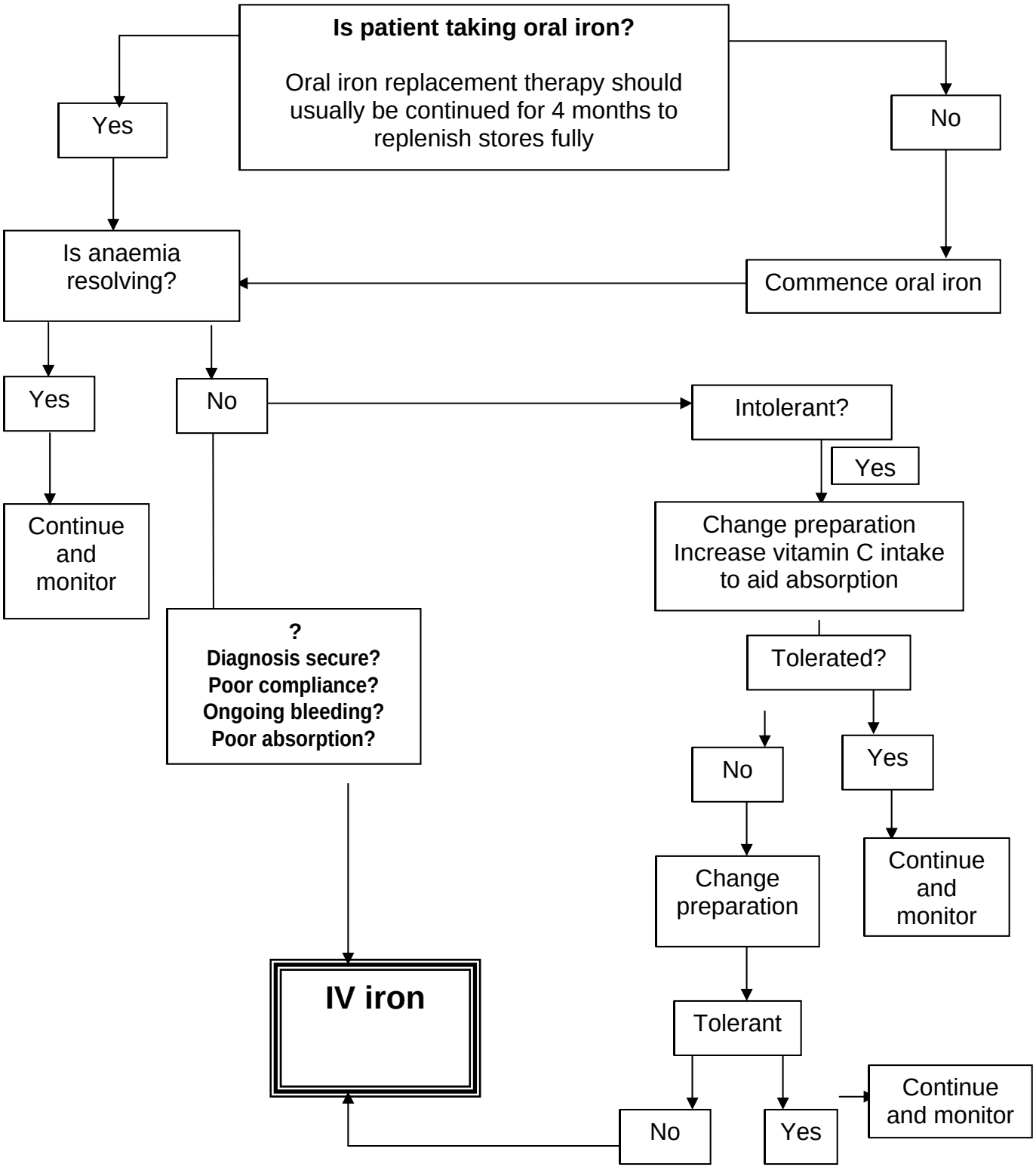
Oral iron must not be administered concomitantly with a course of IV iron. Allow a period of 5 days after the final dose of iv iron.

1.3 Contraindications

- Anaemia not attributable to iron deficiency
- Iron overload
- A history of hypersensitivity to parental iron preparations
- History of cirrhosis of the liver
- Acute or chronic infection
- First trimester of pregnancy
- Acute renal failure
- Patients with a history of severe asthma, eczema or other atopic allergy

1.4 Flowchart for the use of iron in confirmed iron deficiency anaemia

(Full blood count + film, Reticulocyte count, Iron profile, CRP, In addition B12 and folate may be indicated)



1.5 IV iron preparations available

There are two preparations of IV iron available;

IV iron sucrose (Venofer®) given as a divided dose, and low molecular weight iron dextran (CosmoFer®) this can be given as a total dose infusion (CosmoFer ® may also be given intramuscularly).

Choice of preparation is dependent on patient and physician choice and how immediate the requirement to complete the dose i.e. iron dextran (CosmoFer ®) can be given as a total dose infusion, iron sucrose (Venofer ®) is given as divided doses. **THIS PROTOCOL REFERS TO IV IRON SUCROSE (VENOFER®)**

1.6 Response

Due to iron metabolic pathways, a rise in reticulocyte count will occur during the second week and thereafter, provided bleeding is not excessive, one can expect a rise in haemoglobin of approximately 1.5g/week.

2 Protocol for Intravenous iron sucrose - Venofer®

2.1 Dosage

The total cumulative dose of Venofer® should be calculated using the table below. Venofer® can be given as a maximum of 200mg not more than 3 times per week; doses must be 24 hours apart.

Total cumulative Venofer® dose = number of 100mg ampoules for Hb increase.

Dose includes 500mg to replenish iron stores.

Increase in Hb required (g/dL) ie Target Hb minus Actual Hb								
		1g	2g	3g	4g	5g	6g	7g
Body weight (kg)	40	6	7	8	9	10	11	12
	45	6	7	8	9	10	11	12
	50	6	7	9	10	11	12	13
	55	6	8	9	10	12	13	14
	60	6	8	9	11	13	14	16
	65	7	8	10	11	13	14	16
	70	7	8	10	12	13	15	17
	75	7	9	10	12	14	16	18
	80	7	9	11	13	15	17	18
	85	7	9	11	13	15	17	19
	90	7	9	11	14	16	18	20
	95	7	10	12	14	16	19	21
	100	7	10	12	15	17	19	22

2.2 Test dose

The first infusion of Venofer® must include a test dose; facilities for cardiopulmonary resuscitation should be available. (Refer also to section 3 – Adverse events). 25mg of Venofer® should be infused over a period of 15 minutes. If no adverse events occur during the test dose, the remainder of the dose should be given at an infusion rate of not more than 50ml in 15 minutes.

Drug to diluent concentration	Test dose	Remainder of first dose
100mg Venofer® in 100mL Sodium Chloride 0.9%	25mg in 25mL over 15 mins. (IV pump set 100mls/hr, VTBI 25mL)	75mg in 75mL to be infused. Max infusion rate 200mL/hr
200mg Venofer® in 100mL Sodium Chloride 0.9%	25mg in 12.5mL over 15 mins. (IV pump set 50mL/hr, VTBI 12.5mL)	175mg in 75mL to be infused. Max infusion rate 200mL/hr
200mg Venofer® in 200mL Sodium Chloride 0.9%	25mg in 25mL over 15 mins. (IV pump set 100mL/hr, VTBI 25mL)	175mg in 175mL to be infused. Max infusion rate 200mL/hr

2.3 Subsequent doses

Subsequent doses may be given over 15minutes (100mg) or 30 minutes (200mg).

Administration	
IV infusion	**Rate of administration**
100mg in 100mL Sodium Chloride 0.9%	Administer over at least 15 minutes (maximum pump rate 400mL/hr)
200mg in 100mL or 200mL of Sodium Chloride 0.9%	Administer over at least 30 minutes (maximum pump rate 200mL/hr for 100mL bag, 400mL/hr for 200mL bag)

2.4 Example dosing

72 kg patient; current Hb 8.2g/dL, target Hb 11g/dL - values should be rounded to the nearest whole number as per the dosage chart. ie 70 kg patient Hb 8g/dL increase required in Hb is 3g/dL.

Dose required is 10 ampoules i.e. 1g (1000mg).

Administer as:

- First dose of 100mg (to include test dose)
- Two further doses of 200mg in first week (cumulative total 500mg)
- Three doses in second week (two of 200mg and one of 100mg)

NB in obese patients, ideal body weight should be used, in antenatal, pre-pregnancy weight should be used.

3 Adverse events

Adverse reactions are rare, however facilities for dealing with anaphylaxis and cardiopulmonary resuscitation should be available.

It is recommended that the anaphylaxis box is kept in the close vicinity of a patient receiving IV iron and that administration is carried out by a health care professional who is IV certified and has attended the Trusts anaphylaxis study day or received training in the management of anaphylaxis.

Adverse drug reactions in clinical trials were; transient taste perversion, hypotension, fever and shivering, injection site reactions and nausea, occurring in 0.5 to 1.5% of patients. Non-serious anaphylactoid reactions occurred rarely.

3.1 Management of adverse events

In the event of a serious anaphylactic or allergic reaction stop the infusion/ IM adrenaline should be administered and appropriate resuscitation measures initiated.

Mild allergic reactions should be managed by stopping the infusion and administering antihistamines.

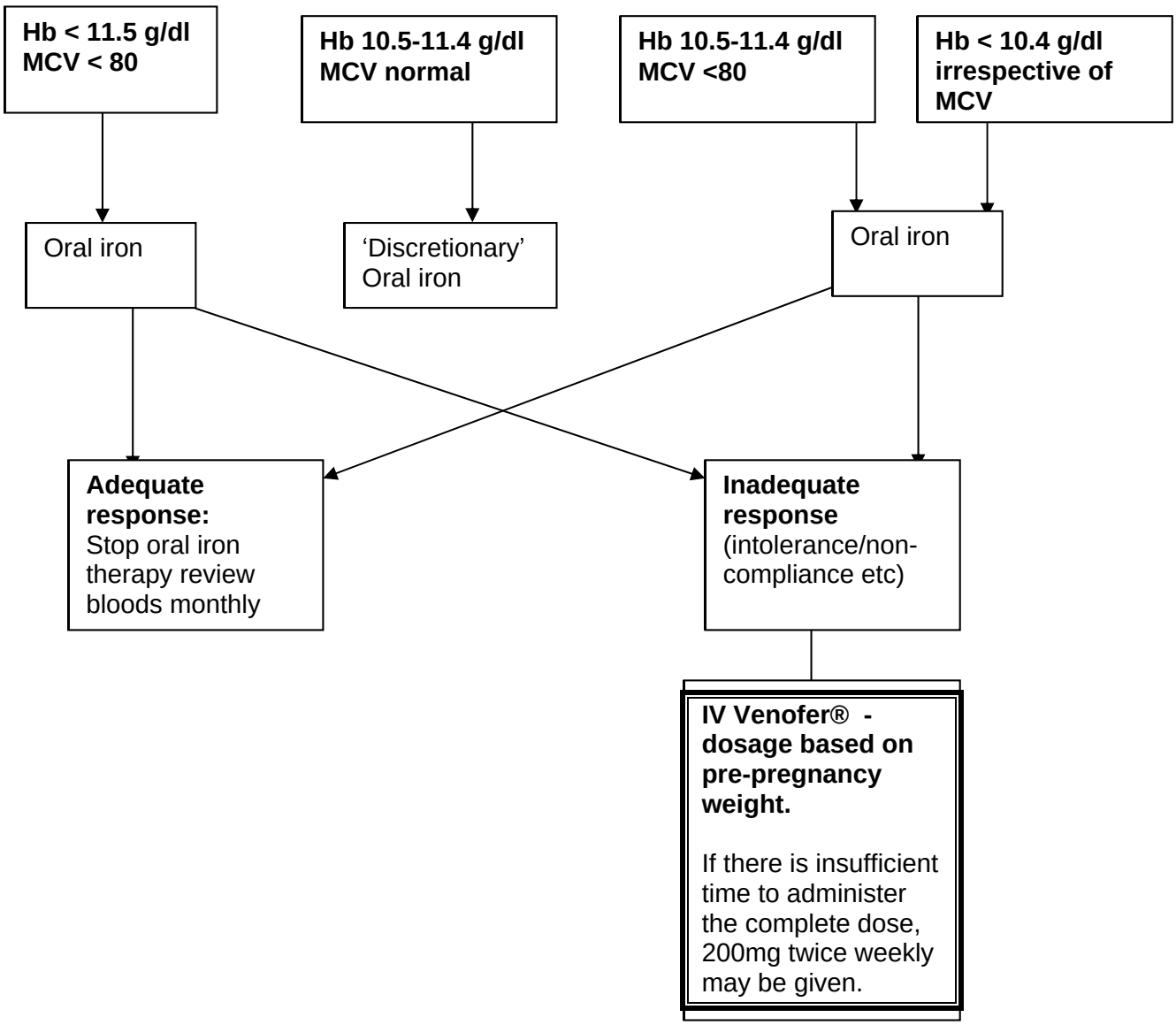
Hypotensive episodes may occur if administration is too fast, so decrease infusion time as clinically indicated.

4 Treatment of obstetric patients with Venofer®

Dosing for antenatal patients should be based on pre-pregnancy weight (or ideal body weight if obese prior to pregnancy). IV iron must not be used in the 1st trimester of pregnancy.

4.1 Antenatal treatment (2nd and 3rd trimester only)

The following flow chart suggests the steps to be followed for anaemia in pregnancy. **Cases should be assessed on an individual basis with discussion between obstetrician, midwife and patient as appropriate.**



4.2 Postpartum treatment.

3 doses of 200mg Venofer® administered as IV infusion 24 hours apart.

A study of postpartum patients on the above regime (Gravier 1999), with an average haemoglobin of 7.1g/dL, demonstrated a mean increase in haemoglobin of 2.2g/dL by day 7 and 3.9 g/dL by day 14.

Non-metabolised iron (III)-hydroxide sucrose complex is unlikely to pass into the mothers' milk. Therefore Venofer® should not present a risk to the suckling child

5 Follow-up

Full blood count, reticulocyte and iron profile should be checked 3 to 4 weeks after the final dose of Venofer® *where follow up is indicated*.

References

Venofer® data sheet

Gravier A (1999) How to avoid transfusion in the postpartum: Intravenous iron supplementation. J Gynecol. Obstet. Biol. Reprod 28, 77-78