Hinchingbrooke Health Care NHS
NHS Trust

Protocol for the use of Intravenous Iron Dextran (CosmoFer®)

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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 levels 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 are not tolerated or contraindicated
- Patient non-compliance with oral iron therapy

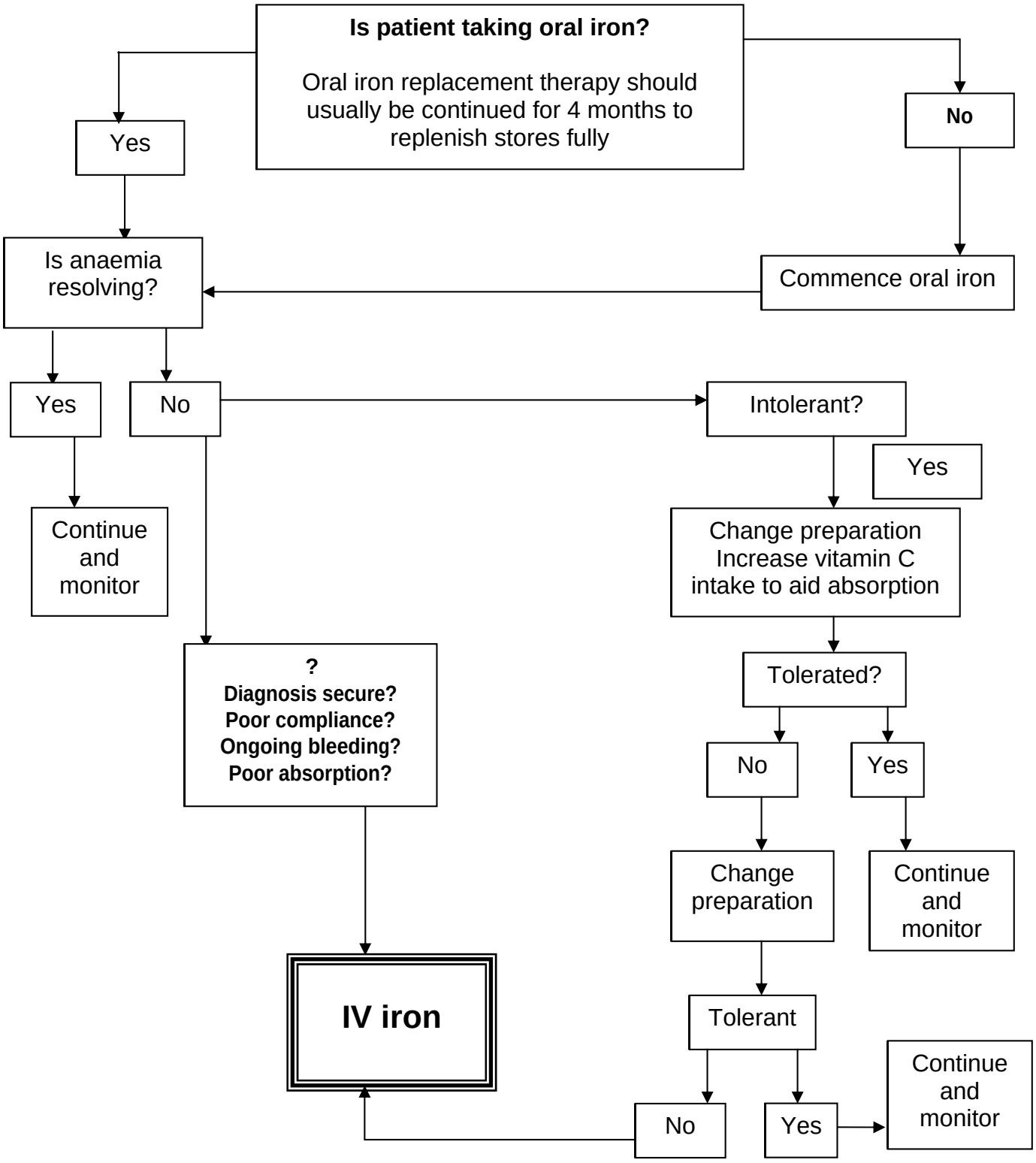
Oral iron must not be administered concomitantly with a course of IV iron or until 5 days after the last dose.

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
- Active rheumatoid arthritis
- First trimester of pregnancy
- Acute renal failure
- Patients with a history of severe asthma, eczema or other atopic allergy
- Drug hypersensitivity including mono- or di-, saccharide complexes and dextran

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

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



1.5 IV iron preparations available

There are two preparations of IV iron available;

IV iron sucrose (Venofer®) given as divided dosages, and low molecular weight iron dextran (CosmoFer®) this can be given as divided dose or 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 LOW MOLECULAR WEIGHT IRON DEXTRAN (COSMOFER®)**

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 dextran - CosmoFer®

2.1 Dosage - Total dose infusion

The dose calculation for CosmoFer® is based on patient's body weight according to the table below and is diluted in 500mLs of normal saline.

If calculating the dose for an obstetric patient, use the pre-pregnancy weight. For obese patients use ideal body weight.

2.2 How to select the correct dose of CosmoFer®

In the left hand column, find the body weight closest to the patient's body weight, read across this row to the column headed by the patients current haemoglobin value, **values for body weight and haemoglobin must be rounded up or down to the nearest stated value**. The number at this point is the dose required (in milligrams of iron).

Note: If the dose is shaded in grey, it exceeds the total upper limit for total dose infusion (20mg/kg body weight) and must be administered as a divided dose. (See section 2.3)

CosmoFer® must be added to 500mLs of Sodium Chloride 0.9% IV infusion and infused over 4 to 6 hours. The patient should be observed for 1 hour after completion of the infusion.

	Actual Haemoglobin (g/dl)					
Body weight (kg)	**7**	**8**	**9**	**10**	**11**	**12**
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	1575	1350	1125	925	700

Example 74kg, current Hb 8.2g/dl – **use body weight 75kg and Hb 8g/dl** dose is 1400mg iron (28mLs Cosmofer® injection) in 500mLs Sodium Chloride 0.9%

2.3 Dosage – Total dose infusion exceeding 20mg/Kg

If the required dosage exceeds 20mg/kg, then it should be given on two separate days. This can be done by:

- Giving half the dose on each day
- Giving up to 20mg/kg in the first infusion, then the reminder in the second infusion.

One week for every 600mg of iron given in the first infusion should be allowed between the first and second doses. For example if 1200mg of iron was given in the first dose, then the second infusion containing the remaining iron should be given 2 weeks later.

2.4 Test dose

The first infusion of CosmoFer® must include a test dose; facilities for cardiopulmonary resuscitation/treatment of anaphylaxis, should be available. (Refer also to section 4 – Adverse events)

25mg of CosmoFer® should be infused over a period of 15 minutes. The patient should then be observed for one hour. If no adverse reactions are seen, give the remaining dose. For subsequent doses the 25mg test dose must still be given, however there is no requirement for the one hour observation period.

2.5 Calculating the test dose

The test dose is taken from the complete infusion bag and is calculated as follows:

$$\frac{25\text{mg}}{\text{Total iron in bag (in mg)}} \times \text{total volume in bag (500mls)}$$

Example:

$$\frac{25\text{mg}}{1400\text{mgs}} \times 500\text{mLs} = 9\text{mLs}$$

To set infusion pump:

Amount required (in mL) X 4 = mL/hr

eg 9mLs required over 15 minutes,

Multiply by 4 to get hourly rate = 36mls/hr.

Volume to be infused (VTBI) set as 9mLs, the pump will then alarm after 15 minutes.

2.6 Continuing the infusion

The remainder of the infusion should be given at the following rate:

- 50mLs/hr for the first hour – **if rate of test dose is > 50mL/hr continue first hour at test dose rate**
- 100mL/hr for the next hour
- 150mL/hr until infusion complete

3 Patient monitoring

Blood pressure and pulse should be monitored prior to the infusion and every 15 minutes during the test dose and observation period.

For the remaining dosage, BP and pulse should be monitored every 30 to 60 minutes or as clinically indicated.

4 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 be kept in the close vicinity of the patient receiving IV iron. Administration should be carried out by nurses or midwives who are IV certified and who have attended the Trusts anaphylaxis study day or received training in the management of anaphylaxis.

- Acute, severe anaphylactoid reactions are uncommon. They usually happen within the first few minutes of administration and are generally characterised by the sudden onset of respiratory difficulty and/or cardiovascular collapse.
- Less severe manifestations of immediate hypersensitivity are also uncommon and include urticaria, rashes, itching, nausea and shivering.
- Delayed reactions are characterised by arthralgia, myalgia and sometimes fever. Symptoms may last 2 to 4 days and settle spontaneously or following the use of simple analgesics such as paracetomol.
- Exacerbation of joint pain in rheumatoid arthritis can occur
- Local reactions such as phlebitis around the administration site may occur.

4.1 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.

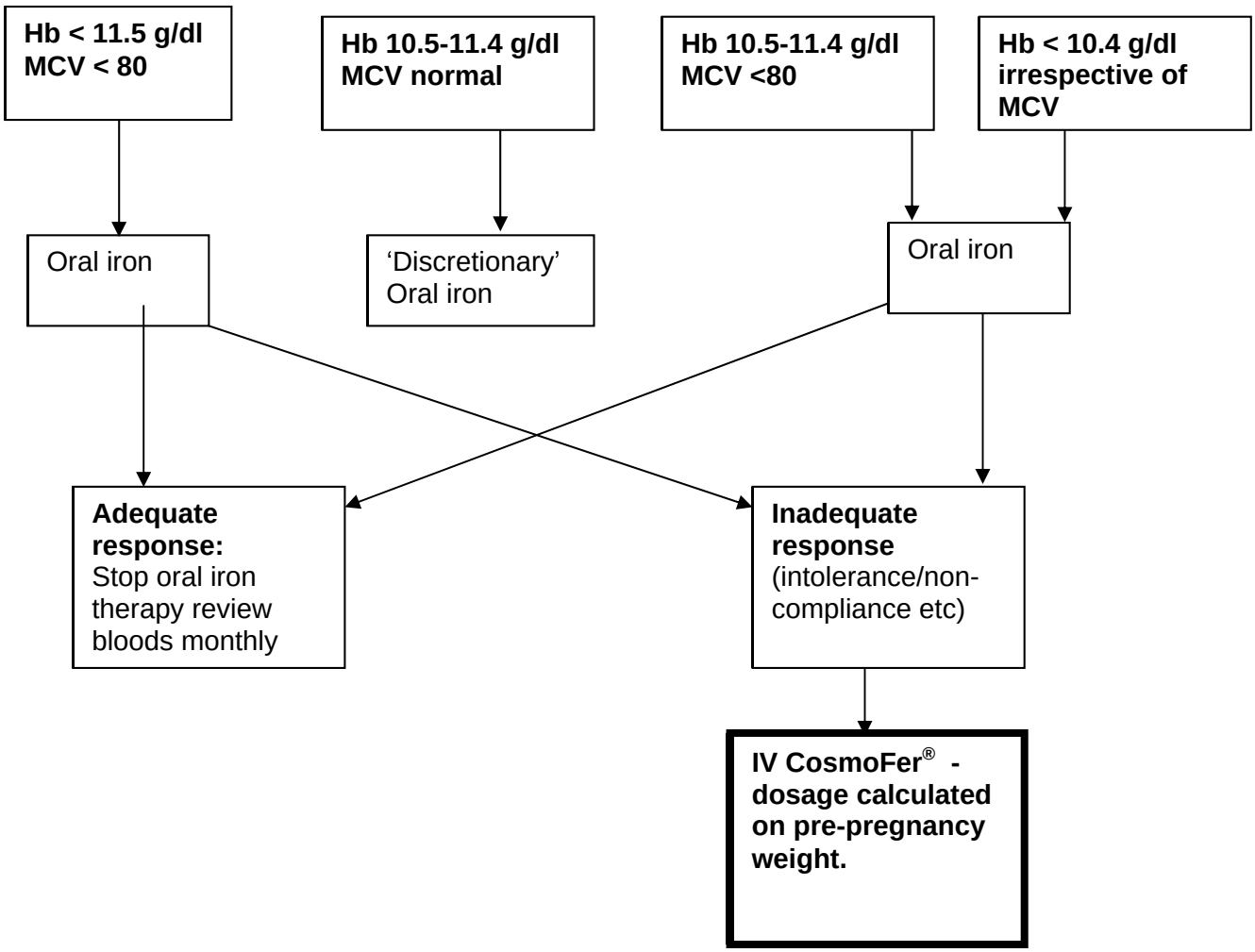
Hypotensive episodes may occur if administration is too fast, so decrease infusion time as clinically indicated.

5 Treatment of obstetric patients with CosmoFer®

CosmoFer® should not be used during the first trimester but can be used during the second and third trimester and during lactation if oral iron therapy is ineffective or impracticable. Dosing for antenatal patients should be based on pre-pregnancy weight (or ideal body weight if obese prior to pregnancy).

5.1 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**.



6 Follow-up

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

References

CosmoFer® model protocol and data sheet Vitaline Pharma UK June 6 2007