Management and Pathway for Intravenous Iron

Classification :	Management Pathway
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Authors Job Title:	Specialist Practitioner of Transfusion (CS) Pharmacy Manager (DW)
Authors Division:	MEDICINE
Departments/Groups This Document Applies to: All Clinical and Ward Areas	
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Approval Signature: Prescribing and Medicines Governance Committee	

Unique Identifier: PHARM/GL/35	**Status:** Approved	**Version No:** 2
Scope: All prescribers, nursing and pharmacy staff within Milton Keynes University Hospital NHS Foundation Trust	**Document for Public Display:** No	
To be read in conjunction with the following documents:		
Required CQC evidence? Fundamental Standard Regulation 9 (Person Centred-Care)	**Key CQC Question:** Safe	

Disclaimer

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.

The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

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Policy Statement

To speed the process of admitting and administrating Intravenous (IV) Iron this pathway has been designed to support the admission of medical and surgical patients to increase the haemoglobin (Hb) level in iron deficient patients.

Executive Summary

The pathway will address this current variation and it will also reduce clinical risk of patients receiving red cells and support patients that refuse blood products, i.e., Jehovah's Witness patients.

Key points covered in this policy

- To identify patients' anaemia prior to surgery with adequate time for treatment.
- To reduce the number of patients who are significantly anaemic at surgery
- To reduce the need for transfusion both pre- and peri-operatively
- The Medicines and Healthcare Regulatory Authority (MHRA) drug safety update: Intravenous iron and hypersensitivity reactions
- Correction of anaemia in pregnancy that is refractory to oral iron

Overall responsibility for the document

The Trust Transfusion Committee and Specialist Practitioner of Transfusion will take lead responsibilities for - Coordinating the development, implementation, review and upkeep of the document.

1.0 Roles and Responsibilities

The document applies to the following group of people

- **Medicine Matron**: Their role is to contact PCU to book a bed
- **Planned Care Unit**: Their role is to inform admissions and to deliver the patients treatment (surgical/obstetrics/ gynaecology patients)
- **Surgery/Obstetrics/Gynaecology Consultants and their teams**: role is to prescribe IV iron in accordance with this guideline, organise the admission of the patient by contacting the medical matron and sending prescription requests to pharmacy before patient is admitted. Informing their own secretaries to ensure their team is available on the day of admission to treat these patients.
- **Haematology consultants and their teams:** role is to prescribe IV iron in accordance with this guideline, arrange for administration via the MacMillan in agreement with the unit manager/senior nurse in charge, as a day case
- **Pharmacy**: Checking the prescription is in accordance with this guideline and supplying the Iron
- **Pre-Assessment**: To inform Surgeon that the patients Hb is reduced and for them to advice team of iron pathway to arrange further management ensure prescription chart available.(Contact Matron of medicine to book a bed if requested to do so) .

2.0 Implementation and dissemination of document

Disseminate to all Clinical Directors, Modern Matrons and Bed Managers. Document will be available on the Intranet.

An e-mail with link to the location of the document will be circulated to all acute user groups within the Trust.

3.0 Principles

Treatment with intravenous iron is indicated in the following situations:

- Treatment of iron deficiency when oral iron preparations are ineffective or cannot be tolerated.
- There is a clinical need to rapidly deliver iron to iron stores.
- In active inflammatory bowel disease where there is intolerance to oral iron preparations.
- A demonstrated non-compliance with oral iron therapy.

This document was in response to the Health Service Circular "Compliance with Better Blood Transfusion '(HSC 2002/009)". It replaced HSC 1998/224 "Better Blood Transfusion" and was then superseded in 2012 with Patient Blood Management. The guidance sets out a new programme as part of clinical governance responsibilities to make blood transfusion safer. Trusts need to ensure that "Better Blood Transfusion" is an integral part of NHS care.

- Avoid unnecessary use of blood in clinical practice
- Provide better information to patients and the public about alternatives to blood transfusion.

Patients that are unable to receive blood products will require oral or intravenous iron to manage their anaemia. It is widely accepted that there is a correlation between higher pre-operative haemoglobins and a reduced need for peri-operative transfusion. It has also been suggested that allogeneic peri-operative transfusions may alter the incidence of disease recurrence or otherwise induce a poorer prognosis in patients undergoing surgery.

The MHRA released a drug safety update in August 2013, following a Europe-wide review of intravenous iron products for iron deficiency and anaemia. The MHRA have recommended that strengthened measures are taken to manage and minimise the risk of hypersensitivity reactions, which may be life-threatening or fatal.

Advice for healthcare professionals:
The prescribing, dosing, administration, and safety information differs between IV iron product formulations, and the individual product information should be consulted before and during use.

Prescribing

- An IV iron product should not be used in patients with known hypersensitivity to the active substance, the product itself, or any of its excipients; it should also not be used in patients with known serious hypersensitivity to any other parenteral iron product
- The risk of hypersensitivity is increased in patients with: known allergies (including drug allergies); immune or inflammatory conditions (e.g., systemic lupus erythematosus, rheumatoid arthritis); or those with a history of severe asthma, eczema, or other atopic allergy. In these patients, IV iron products should only be used if the benefits are clearly judged to outweigh the potential risks
- IV iron should only be used during pregnancy if clearly necessary. Treatment should be confined to the 3rd trimester, if the benefit is clearly judged to outweigh the potential risks for both mother and foetus
- Please discuss with pharmacy medicines information for advice on intravenous iron in pregnancy

Administration and monitoring

- IV iron should be administered in strict accordance with the posology and method of administration described in the product information for each individual product (note that advice varies between products)
- Caution is needed with every dose of intravenous iron that is given, even if previous administrations have been well tolerated
- IV iron products should only be administered when staff trained to evaluate and manage anaphylactic or anaphylactoid reactions—as well as resuscitation facilities—are immediately available
- Patients should be closely monitored for signs of hypersensitivity during and for at least 30 minutes after every administration of an IV iron product
- In the event of a hypersensitivity reaction, treatment should be stopped immediately and appropriate management initiated

Test dose

- Previously, an initial test dose has been recommended for some IV iron products before administration of the first dose to a new patient. However, there are no clear data that an initial test dose minimises risk: conversely, it may give false reassurance because hypersensitivity reactions have been reported in patients that had a negative initial test dose.
- Please refer to the drug's summary of product characteristics for further information on administration of test doses.

Information for patients

- Healthcare professionals should inform patients of the risk and potential seriousness of a hypersensitivity reaction before every administration and document this discussion in the notes. Patients should be informed of the relevant symptoms and advised to tell their doctor or nurse straight away if any of these occur

Reporting of suspected adverse drug reactions

- The safety of IV iron products will continue to be monitored closely in the UK and Europe. Any suspected adverse reactions to IV iron products should be reported via the Yellow Card Scheme. Please ensure to include the name of the specific product administered (www.mhra.gov.uk/yellowcard)

4.0 Process and Procedure

A full blood count (FBC) should be performed on all patients undergoing major surgery where blood loss is expected (NICE CG3 2003). These include consideration of when a FBC is necessary. These tests should be carried out **as soon as possible** (first outpatient appointment preferable as time is then available to optimise Hb)

4.1 Iron Deficiency Anaemia (IDA)

The cause of IDA may already be known, if not, the reason for IDA must be investigated in order to identify any other serious underlying causes such as colon cancer.

It is important that as well as correcting the anaemia, iron stores are replenished. This is particularly important for patients undergoing surgery where blood loss is expected.

Often the best way to confirm true IDA is by trial of oral iron for three weeks, or parenteral iron if poor compliance. A measurable change in MCH should occur within 7 days when there is true IDA. Obtain actual or estimated time of surgery.

If patient is intolerant/ unable to absorb oral iron tablets or if the patient has continued blood loss there needs to be discussion with the clinicians regarding optimal pre-surgical Hb and consideration of IV Iron.

4.1.2 Pregnancy

A FBC is routinely measured at booking and 28 weeks in all pregnancies (NICE recommendation). In addition during pregnancy physiological haemodilution occurs. Pregnant women showing evidence on red cell indices should initially be treated with oral iron. When investigating women with anaemia in pregnancy, consideration should be given to the possibility of co-existing folate deficiency, particularly in multiple pregnancy.

Please refer to the Royal college of Nursing (RCN) guidance 'Iron deficiency and anaemia in adults' (2015), the British Committee for Standards in Haematology (BCSH) UK guidelines on the management of iron deficiency in pregnancy (2011) and The Royal College of Obstetricians and gynaecologists (RCOG) 2010 guideline for nutrition in pregnancy, for further information.

4.2 Red cell indices:

These are performed as part of a routine FBC and the following are highly suggestive of iron deficiency anaemia:

- Microcytic RBC (MCV <76)
- Hypochromic RBC (MCH <27)

These indices, especially in conjunction with a raised RBC, are also indicative of haemoglobinopathies, and this should be ruled out in patients of certain ethnic origin. N.B. caution use of IV iron in some haemoglobinopathies due to the risks of haemosiderosis.

4.3 Serum Ferritin:

Serum ferritin is one of the primary diagnostic tests for iron deficiency. A serum ferritin of <15 ug/dL indicates iron deficiency. However these measurements may be unreliable in patients with concurrent acute or chronic inflammatory conditions. In these cases a ferritin < 50ug/dl with an elevated CRP is still indicative of IDA. (Taken from Guidelines for the management of iron deficiency anaemia BSG Guidelines in Gastroenterology May 2005).

4.4 Treatment:

IDA can be treated in two ways:

1. **Oral iron therapy**: this is the preferred treatment and should always be the first choice. (Appendix 1)
2. **Parenteral (IV iron)** (Appendix 2 and 4)

   Parenteral Iron should only be used when:

   - Oral iron is not tolerated
   - Oral iron cannot be absorbed
   - Patient has continued blood loss

4.5 Rationale for main recommendations

There needs to be appropriate pre-operative planning for patients that have a low Hb and the opportunity to raise it with iron rather than red cells. There is a decrease in blood donors and the need to protect this valuable resource ensuring it is available for patients when there is no other choice of treatment.

5.0 Statement of evidence/references

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2. Pharmacosmos UK Limited. (2014) CosmoFer [50mg/ml solution for infusion and injection]. SPC (Summary of Product Characteristics). [Online]. Available from: http://www.medicines.org.uk/emc/medicine/14139 [Accessed 19 February 2016]
3. A Model Protocol for the administration of a total dose infusion of Iron (III)-hydroxide dextran complex (CosmoFer), for the treatment of iron deficiency anaemia. July 2007. Vitaline Pharma UK. via http://journals.rcni.com/doi/full/10.7748/ns2008.08.22.48.35.c6635
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6. Goddard, A.F., James, M.W., McIntyre, A.S. and Scott, B.B. on behalf of the British Society of Gastroenterology. (2011) Guidelines for the management of iron deficiency anaemia. Gut. 60:1309e1316. doi:10.1136/gut.2010.228874. Available from: http://www.bsg.org.uk/images/stories/docs/clinical/guidelines/sbn/bsg_ida_2011.pdf [Accessed 19 February 2016]
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9. British Committee for Standards in Haematology. (2011) UK guidelines on the management of iron deficiency in pregnancy. [Online]. Available from: http://www.bcshguidelines.com/documents/UK_Guidelines_iron_deficiency_in_pregnancy.pdf [Accessed 19 February 2016]
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11. Royal College of Obstetricians and Gynaecologists. (2010) Nutrition in pregnancy. [Scientific Impact Paper 18] [Online]. Available from: https://www.rcog.org.uk/globalassets/documents/guidelines/scientific-impact-papers/sip_18.pdf [Accessed 19 February 2016]
12. Royal College of Obstetricians and Gynaecologists. (2015) RCOG statement: Advice on nutrition in pregnancy. [Online]. Available from: https://www.rcog.org.uk/en/news/rcog-statement-advice-on-nutrition-in-pregnancy/ [Accessed 16 February 2016]
13. Care Quality Commission. (2015) *Regulation 9: Person-centred care. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 9.* [Online]. Available from: http://www.cqc.org.uk/content/regulation-9-person-centred-care [Accessed 19 February 2016]
14. http://www.transfusionguidelines.org.uk/uk-transfusion-committees/national-blood-transfusion-committee/patient-blood-management [Accessed 19 February 2016]

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6.0 Governance

6.1 Record of changes to document

Version number: 2		**Date:** September 2015		
Section Number	**Amendment**	**Deletion**	**Addition**	**Reason**
1.0	Addition of roles of haematology team		✓	Review
3.0	Inclusion on MHRA drug safety alert		✓	Review
Appendix 4	Addition of appendix 4: Ferrous Carboxymaltose (Ferinject)		✓	Review

6.2 Consultation History

Stakeholders Name/Board	**Area of Expertise**	**Date Sent**	**Date Received**	**Comments**	**Endorsed Yes/No**
	Specialist Practitioner of Transfusion		Jan 2008	Author: Need for a pathway to reduce risk and reduce the need for red cells.	Yes
	Formulary services Manager		Jan 2008	Input on drug management and ensure compliance with Trust formulary	Yes
	Pharmacy Manager, Cancer and Aseptics		June 2015	Policy review, Addition of roles of haematology team, Inclusion on MHRA drug safety alert, Addition of appendix 4: Ferrous Carboxymaltose (Ferinject)	Yes
Pharmacy CIG	Specialists in the use and management of medicines	September 2015	Septembe r 2015	To take to maternity and acute medicine CIG	Yes

	within MKHFT				
	Consultant Haematologist	September 2015			
	Consultant Haematologist	September 2015		Comments received – list indication for iv iron	Yes
	Haematology Registrar	September 2015		Comments received	Yes
	Consultant Haematologist	September 2015			
	Haematology Registrar	September 2015			
	Consultant Obstetrics and Gynaecology	November 2015		Comments received	Yes
Clinical Board	Senior Doctors - responsibility for governance of prescribing in their area	October 2015			
Maternity CIG		February 2016		Comments received	Yes
Acute medicine CIG		February 2016		Comments received	Yes
	Clinical Director, Women's & Children's	February 2016		Comments received	Yes

6.3 Audit and monitoring

This Policy outlines the process for document development will be monitored on an ongoing basis. The centralisation of the process for development of documents will enable the Trust to audit more effectively. The centralisation in recording documents onto a Quality Management database will ensure the process is robust.

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board
a) Patients are admitted to the appropriate area in enough time to optimise Hb pre-operatively	statistics and a report	Specialist Practitioner Of Transfusion	Annually	a) Hospital Transfusion Committee
b) Correct testing and diagnosis being made before admission for IV iron.	statistics and a report	Specialist Practitioner Of Transfusion	Annually	b) Hospital Transfusion Committee

6.4 Equality Impact Assessment

This document has been assessed using the Trust's Equality Impact Assessment Screening Tool. No detailed action plan is required. Any ad-hoc incident which highlights a potential problem will be addressed by the monitoring committee.

Impact	**Age**	**Disability**	**Race**	**Gender**	**Religion or Belief**	**Sexual Orientation**
Do different groups have different needs, experiences, issues and priorities in relation to the proposed policy?	No	Yes	No	No	No	No
Is there potential for or evidence that the proposed policy will not promote equality of opportunity for all and promote good relations between different groups?	No	No	No	No	No	No
Is there potential for or evidence that the proposed policy will affect different population groups differently (including possibly discriminating against certain groups)?	No	No	No	No	No	No
Is there public concern (including media, academic, voluntary or sector specific interest) in potential discrimination against a particular population group or groups?	No	No	No	No	No	No

Race Equality Scheme Policy Impact Assessment Proforma

Directorate:	Pathology
Policy Title:	Management and Pathway for Intravenous Iron
Date of Review:	September 4th 2007
Reviewed by:	Specialist Practitioner of Transfusion

Impact Assessment should address the following questions

	Question	Yes	No
1	Is there evidence of higher or lower participation or uptake by different groups?		√
2	Is there an opportunity to promote equality of opportunity or good race relations by altering the policy or working with others?		√
3	Are there indications, from consultation with relevant groups, organisations or individuals, that the policy may create problems that are specific to them?		√
4	Is there evidence that different groups have different needs, experience, issues and priorities in relation to the policy area?	√	
5	Is there evidence or reason to believe that some racial groups could be adversely affected?		√
6	Is there any user, carer or staff concern that the policy is being carried out in a discriminatory way?		√

If any of the questions are answered yes, an action plan must be put in place to address the situation.

Action to be taken	Lead	Timescale
This policy should be used alongside the Jehovah Witness /patients refusing blood products policy.	Specialist practitioner of Transfusion.	Whenever needed

7.0 Standards for Better Health

Domain	Definition/Evidence
Safety	Reduction in red cells with the theoretical and known risks of blood transfusion Reducing risk to patients regarding anaphylaxis by treating patients in a clinical area
Clinical and Cost Effectiveness	Reduced hospital stay if patients Hb Is pre-optimised
Governance	All providers of health services have in place the managerial and clinical leadership and accountability, the organisational culture, and the systems and working practices to enable probity, quality assurance, quality improvement and patient safety to be the central components of all routines, processes and activities.
Patient Focus	Health care is provided in partnership with patients, their carers and relatives and is designed around decisions which respect their diverse needs, preferences and choices
Accessible and Responsive Care	Patients receive services as promptly as possible, have choice in access to services
Care Environment and Amenities	Care is provided in environments that promote patient and staff well-being and respect for patients' needs and preferences in that they are designed for the effective and safe delivery of treatment, care or a specific function (such as catering or pharmacy), accord an appropriate degree of privacy, are well maintained and are cleaned and optimise health outcomes.
Public Health	Health care organisations provide leadership, and collaborate with relevant local organisations and communities to ensure the design and delivery of programmes and services, which promote, protect and improve the health of the population and reduce health inequalities between different population groups and areas.

Appendix 1: Treatment Oral Iron Therapy

Oral iron

Therapeutic response the haemoglobin should rise by about 1-2 g/l per day.

When the haemoglobin is normal, treatment should continue for a further 3 months to replenish stores.

Recommended dose (as per BNF guidance):

Preparation	(mg)	Elemental iron	Therapeutic Dose
Ferrous sulphate, dried tablet	200	65	1 tablet three times daily
Ferrous fumarate tablet	210	68	1 tablet three times daily
Ferrous Fumarate liquid	140	45	10mL twice a day

Please refer to the Milton Keynes Formulary for further information:

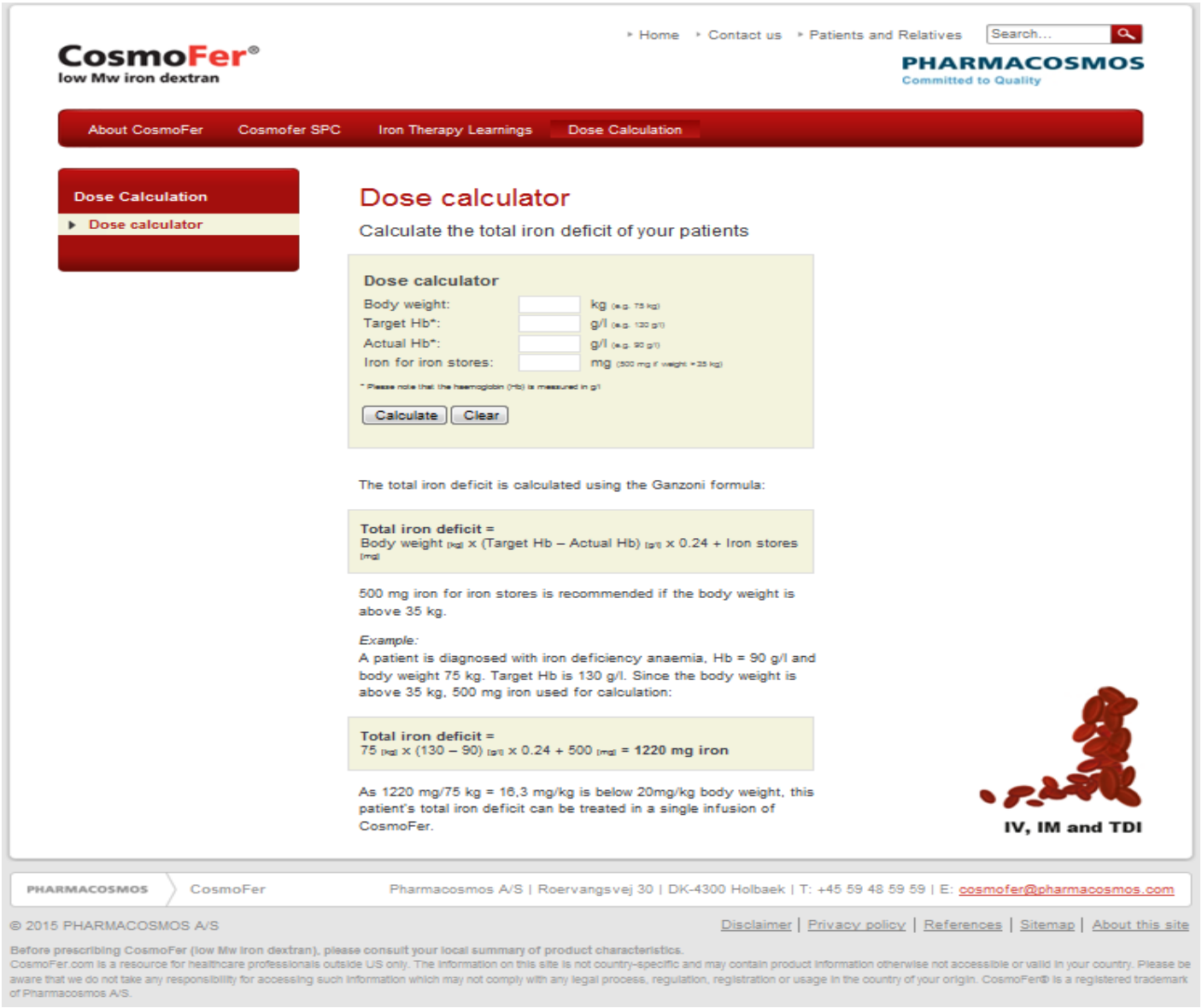
http://formularymk.nhs.uk/911-Iron–deficiency-anaemias/

Appendix 2: Iron (III) hydroxide dextran complex (CosmoFer®)

CosmoFer® is indicated for the treatment of iron deficiency **in adults only** for the following indications:

- When oral iron preparations cannot be used, e.g. due to intolerance, or in case of demonstrated lack of effect of oral iron therapy
- Where there is a clinical need to deliver iron rapidly to iron stores. The diagnosis of iron deficiency must be based on appropriate laboratory tests (e.g. Serum ferritin, serum iron, transferrin saturation and hypochromic red cells).

To calculate the dose required please see link to the CosmoFer calculator:
http://www.cosmofer.com/product/dose-calculation/dose-calculator.aspx



Pregnant patients: Use pre-pregnancy weight or recorded weight at first hospital visit.

Obese patient: If body weight exceeds 90kg, use ideal body weight.

THE TOTAL DOSE INFUSION OF COSMOFER MG/ML TO BE ADMINSTERED FOR IDA

[(Target Hb – Actual Hb) (g/L) **x Weight** (kg) **x 0.24] + 500mg** (iron stores for pt > 35kg only)

Example; Patient JB

Actual Hb = 8.5g/dl (**85g/L**) Target Hb = 12g/dl (**120g/L**) Body weight = **67kg**

Iron dose required (mg) = [**(120 - 85)** (g/L) **x 67** (kg) **x 0.24**] **+ 500 mg**

= [(35) x 67 x 0.24] + 500 mg

= [562.8] + 500 mg

= 1,062.8 mg (i.e. **21.26 mL of CosmoFer**)

Each ampoule of CosmoFer contains 50mg/mL of Iron, but for ease of administration calculated doses should be rounded down to the nearest half or whole ampoule. Therefore dose for JB should be rounded to **1,050 mg (21 mL of CosmoFer).**

Dilute calculated dose of CosmoFer (1050mg) in 500mL of NaCl 0.9% or Glucose 5%

The maximum single dose infusion is 20mg/kg. If the determined dose of CosmoFer required exceeds the upper limit for TDI of 20mg/kg, then administration will take place **on two separate days, 2 WEEKS APART.**

Example; Patient JB, Body weight = **67kg** Maximum for TDI = 20mg/kg

= 20 x 67

= **1,340 mg**

Calculated Iron dose required (mg) = **1,050 mg (21 mL of CosmoFer).**The calculated dose does not exceed the maximum; JB's dose can be administered on one occasion.

A **TEST dose** of 25mg of CosmoFer should then be administered **over 15 minutes** via an infusion pump. The volume of liquid (ml) in the bag that contains 25mg of iron can be determined by:

$$\textbf{Test dose} = \frac{25\text{mg}}{\text{Total iron in bag (mg)}} \times \text{Total volume in bag (mL)}$$

Example; Patient JB

Total volume in bag containing 25mg = $\frac{25\text{mg}}{1{,}050\text{ (mg)}}$ **x** 521 (mL) ← (500ml diluent + 21mL cosmoFer required)

= **12.4 mL (test dose) to be administered over 15 minutes**

Monitor patient (BP, pulse, temperature) during first 15 minutes of the infusion.
If no adverse reactions occur during this time, then the remaining portion of the infusion can be given intravenously over 4 – 6 hours.

OBSERVATIONS

All patients should be monitored for adverse reactions during their infusion, including those who have previously tolerated IV iron. Monitor the patient for adverse effects during the 15 minute test infusion. Close observations of BP, pulse and temperature recordings must be made. If the patient experiences no adverse effect, the remaining dose should be infused over 4-6 hours. BP, pulse and temperature recordings must be made every hour during the infusion and for one hour after completion of the infusion. Monitor patient for at least 30 minutes after completion of infusion.

Administration must be stopped immediately when signs of an anaphylactic or hypersensitivity reaction occur and a doctor called. In the event of a cardio-pulmonary collapse call 2222.

SIDE EFFECTS

Acute severe anaphylactic reactions are very rare (<1in10,000). They are usually characterised by the sudden onset of respiratory difficulty and/or cardiovascular collapse. Less severe manifestations of immediate hypersensitivity are uncommon and include urticaria, rashes, itching, nausea and shivering.

Delayed reactions are well described and may be severe. They are characterised by arthralgia, myalgia and sometimes fever. The onset varies from several hours up to four days after administration. Symptoms usually last two to four days and settle spontaneously or following the use of simple analgesics**.** The risk is enhanced for patients with known allergies including drug allergies, including patients with a history of severe asthma, eczema or other atopic allergy. There is also an increased risk of hypersensitivity reactions to parenteral iron complexes in patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis)

EFFECTIVENESS OF THERAPY

The patients Hb and Ferritin should be measured no earlier than 3-4 weeks after the last CosmoFer infusion to confirm the predicted increases.

CosmoFer injection should not be administered concomitantly with oral iron preparations.
Oral therapy should not be started earlier than 5 days after the last injection of CosmoFer.

Appendix 3: Medical/ Surgical/ Gynecology Patients IV Iron Infusion Pathway

Iron deficiency identified at Outpatients/Pre assessment with the full blood Count. Give patient following leaflets

1. Iron in your diet
2. Will I need a blood transfusion

Hb < 100g/l
Decision to be made if oral or Intravenous Iron should be given

Intravenous Iron

The patients Hb and Ferritin should be measured no earlier than 3-4 weeks after the last CosmoFer infusion to confirm the predicted increases.

1. Pre-Assessment (if surgical patients) or Medical / Surgical and Gynae team responsible for the patient to **contact Matron** for Medicine who will book **bed with PCU**. They also need to inform their secretary of patient admission so the team are aware of them (No need to go through admissions because the beds on PCU are not part of bed stock) **PCU will inform Admissions office**
2. Admitting Clinician to prescribe Iron in advance of admission and **send prescription for IV** Iron to pharmacy **ready** for patient's admission.

(Note if it is a surgical/Gynaecology patient they will be looked after by the **admitting** team even though they have booked the bed through the medical matrons)

Obstetric cases to be referred to obstetric team for admission to ACU .Then follow protocol from point 2

Oral iron
Therapeutic response the haemoglobin should rise by about 1-2 g/l per day.
Clinician to send a letter to GP recommending a course of oral iron

Patient admitted to Planned Care Unit. On discharge patients need to be given a card for repeat Hb/Ferritin to be rechecked within3-4 weeks at their Doctors surgery.

Appendix 4: Ferric Carboxymaltose (Ferinject)

Ferinject is indicated for treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. The diagnosis must be based on laboratory tests. Patients should be considered for Cosmofer in the first instance, where Cosmofer is deemed unsuitable, the reasons should be documented, and Ferinject can be used as an alternative.

Determination of the cumulative iron dose

The cumulative dose for repletion of iron using Ferinject is determined based on the patient's body weight and haemoglobin (Hb) level. The following table (Table 1) should be used to determine the cumulative iron dose:

Table 1: Determination of the cumulative iron dose

Hb (g/L)	Patients with body weight 35 kg to <70 kg	Patients with body weight ≥70 kg
<100	1,500 mg	2,000 mg
≥100	1,000 mg	1,500 mg

Note: A cumulative iron dose of 500 mg should not be exceeded for patients with a body weight <35 kg.

For overweight patients, a normal body weight/blood volume relationship should be assumed when determining the iron requirement. For patients with a Hb value ≥140 g/L, an initial dose of 500 mg iron should be given and iron parameters should be checked prior to repeat dosing.
Post repletion, regular assessments should be completed to ensure that iron levels are corrected and maintained.

Maximum tolerated single dose

A single dose of Ferinject should not exceed 1,000 mg of iron (20 mL) per day. Do not administer 1,000 mg of iron (20 mL) more than once a week.

Intravenous injection

Ferinject may be administered by intravenous injection using undiluted solution up to 1,000 mg iron (up to a maximum of 15 mg/kg body weight). For doses up to 200 mg iron, there is no prescribed administration time. For doses greater than 200 and up to 500 mg iron, Ferinject should be administered at a rate of 100 mg/min. For doses greater than 500 and up to 1,000 mg iron, Ferinject should be administered over 15 minutes.

Intravenous infusion

Ferinject may be administered by intravenous infusion up to a maximum single dose of 1,000 mg of iron (up to a maximum of 20 mg/kg body weight).

Method of administration

Ferinject must be administered only by the intravenous route: by bolus injection, or during a haemodialysis session undiluted directly into the venous limb of the dialyser, or by infusion. In case of infusion, Ferinject must be diluted only in sterile 0.9% m/V sodium chloride solution as shown in Table 2 below.

Table 2: Dilution plan of Ferinject for intravenous infusion

Ferinject	**Iron**	**Maximum amount of sterile 0.9% m/V sodium chloride solution**	**Minimum administration time**
2 to 4 mL	100 to 200 mg	50 mL	-
>4 to 10 mL	>200 to 500 mg	100 mL	6 minutes
>10 to 20 mL	>500 to 1,000 mg	250 mL	15 minutes

Note: For stability reasons, dilutions to concentrations less than 2 mg iron/mL are not permissible.

Ferinject should only be administered when staffs trained to evaluate and manage anaphylactic reactions are immediately available, in an environment where full resuscitation facilities can be assured. Each patient should be observed for adverse effects for at least 30 minutes following each Ferinject injection. If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately.

Ferinject must not be administered by the subcutaneous or intramuscular route. The use of Ferinject has not been studied in children, and therefore is not recommended in children under 14 years.

Side effects

The most commonly reported ADR is nausea, followed by headache, dizziness, and hypertension. Injection site reactions (common) and hypophosphataemia (common) may occur.