

1. Introduction

Anaemia is a common complication of chronic kidney disease with the prevalence of anaemia increasing as glomerular filtration rate falls. The management of anaemia in CKD for both non-dialysis and dialysis patients often involves the administration of both erythropoietin and iron. In recent years, this has involved increasingly the use of intravenous (IV) iron preparations in both dialysis and non-dialysis patients. A local audit (2012) suggested that there was excessive use of IV iron particularly in non-dialysis CKD patients. Although IV iron has been associated with slightly higher haemoglobin and iron indices as well as lower erythropoietin requirements when compared with oral iron (1), there is a lack of evidence with regards to better patient outcomes. Furthermore, intravenous iron is expensive and inconvenient for patients and has a very small risk of allergic reactions.

In contrast, IV iron has become an established form of therapy for optimising the effectiveness of erythropoietin in patients with renal failure treated by haemodialysis. It is often used for peritoneal dialysis (PD) patients but the evidence for superiority of IV over oral iron is less convincing in this patient group. (1-4). This guideline aims to outline the indications for IV iron in the CKD population. Adequate iron stores ensure the effective and efficient use of erythropoietin. It also contains the administration procedures in the appendices.

Following the 2015 NICE guidance, alternative criteria for assessment of iron deficiency were recommended – either percentage hypochromic red blood cells or reticulocyte haemoglobin content. However, ferritin and TSAT remain the most widely used markers of iron status to guide clinical decision making regarding iron administration (5) and were the indices used to evaluate iron stores in the recently published PIVOTAL Trial (6)

2. Scope

This guideline will be used in the UHL Trust haemodialysis units, renal day case unit and renal wards at the LGH site and other areas where intravenous iron may be administered. It is to be used by registered nursing and medical staff with appropriate renal experience.

Clinical guidelines are ‘guidelines’ only. The interpretation and application of clinical guidelines will remain the responsibility of the individual practitioner. If in doubt, consult a senior colleague or expert.

3. Recommendations

3.1 CKD and PD patients

3.1.1. Indications for iron supplementation in CKD and PD patients

Iron supplementation is recommended in non-dialysis CKD and peritoneal dialysis patients who fulfil the following:-

- Haemoglobin (Hb) less than 110g/L with a ferritin of <100ug/L and a TSAT <20%
OR a Reticulocyte Haemoglobin (CHR) count of less than 29pg.

The reticulocyte Hb content reflects the amount of functional iron available for haemoglobin production in the bone marrow. It is an early, direct measurement of iron status and has greater sensitivity and specificity than ferritin and TSR.

- Patients with Hb >110g/L without the need for erythropoietin will not require iron in the context of CKD.

NB: There is emerging evidence regarding the utility of intravenous iron replacement in other chronic disease states. The European Society of Cardiology now recommends the use of IV iron for symptomatic patients with heart failure and reduced ejection fraction (HFrEF, defined as an ejection fraction of <40%) if their ferritin is <100 ug/L or with a ferritin of 100-299 ug/L and a TSAT of <20% in order to alleviate symptoms, improve exercise capacity and quality of life. (7). Given the increased prevalence of heart failure in the CKD population, administration of IV iron may therefore be indicated for reasons other than CKD-related anaemia.

3.1.2 Oral iron supplementation in CKD and PD patients

Recent national and international guidelines (1-3) have recommended an initial trial of oral iron in CKD and peritoneal dialysis patients not yet on erythropoietin (ESA) who require iron supplementation.

There is no evidence to support the use of one oral iron supplement over another.

Ferrous sulphate is commonly used at a dose of 200mg thrice daily although recent studies of iron-deficient women have shown that providing iron supplements daily as divided doses increases serum hepcidin and reduces iron absorption. Providing iron supplements on alternate days and in single doses optimises iron absorption and might be a preferable dosing regimen (e.g. ferrous sulphate 200mg daily or on alternate days) (8).

If a patient is intolerant of the first oral iron supplement, consider changing to alternative oral preparation (such as ferrous fumarate or gluconate) or an alternate dosing regimen (see above).

The use of oral iron supplements should prompt a review of the patient's medications to identify potential interactions. Particular attention should be paid to calcium supplements and calcium based phosphate binders which affect iron absorption.

If target Hb levels are not reached within 3 months, then a switch to intravenous (IV) iron should be made.

3.1.3 Intravenous iron in CKD and PD patients

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This is recommended in the following:-

1. Patients who fail to tolerate oral supplements
2. Target Hb levels not reached within 3 months of oral iron
3. Patients already on ESA

According to availability/price of iron preparation, local practice and arrangements with commissioners CKD and PD patients are either given:-

- Iron isomaltoside 1000 (Monofer). This has the advantage of permitting full iron loading with a single dose. Up to 20mg/kg can be administered in a single day case visit.
- Iron carboxymaltose (Ferinject) infusion which also has the advantage of permitting full iron loading with a single dose.
- Iron hydroxide sucrose (Venofer) must be given over three visits at 200mg per visit

Due to a small number of anecdotal reports of hypersensitivity reactions following administration of iron isomaltoside in the dialysis units the current practice is to use iron hydroxide sucrose (Venofer) or iron carboxymaltose (Ferinject).

Due to a lack of data, Monofer or Ferinject should not be used in pregnancy unless clearly necessary. Use is confined to the 2nd and third trimester. **(See appendix 4 for administration procedure)**

3.1.4 Dose of iron isomaltoside 1000 (Monofer) or iron carboxymaltose (Ferinject)

The dose of iron isomaltoside 1000 (Monofer) or iron carboxymaltose (Ferinject) should be adjusted according to weight.

Patient Weight	Dose of Iron isomaltoside 1000 (Monofer) or Iron carboxymaltose (Ferinject)
<40kg	15mg/kg
>40kg	600mg

3.2 Unit Based Haemodialysis Patients

3.2.1 Iron supplementation in HD patients

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The recently published *Proactive Intravenous Iron Therapy in Haemodialysis Patients* (PIVOTAL) trial provides convincing evidence that a proactive high-dose IV iron strategy is not only safe but results in a significantly lower risk of death or major nonfatal cardiovascular events and reduces ESA dosing.

The population enrolled were adult HD patients receiving dialysis for <12 months with a ferritin <400 ug/L and TSAT <30% who receiving ESA therapy; they received an initial dose of 600mg IV iron sucrose divided over 3 HD sessions in month one followed by 200mg during each of the first two dialysis sessions (total 400mg per month) thereafter. Safety cut-offs were defined as a ferritin of >700ug/L and/or a TSAT of >40% at which level the iron was withheld and rechecked the following month. Median follow-up was 2.1 years. The clinical effect of this dosing regimen in patients who have been dialysing for >1 year, for those not on ESA therapy or for a duration longer than 4.4 years is uncertain.

In light of these data and the UK Renal Association Guideline published in June 2017 and updated in February 2020, we recommend the use of IV iron for the following HD patients:

- Hb <110g/L and a ferritin <100ug/L in those not receiving ESA therapy
- Patients on ESA therapy with a ferritin <400 ug/L and TSAT <30%
- Patients with Hb >110g/L without the need for erythropoietin do not normally require intravenous iron but may have indications for therapy beyond their CKD (see above).

(See appendix 3 for administration procedure)

3.2.2 Dosing

- Patients will usually receive 200mg of IV iron isomaltoside 1000 (Diafer) or iron hydroxide sucrose (Venofer) during the first two dialysis sessions of the month (after the monthly blood tests) to ensure serum ferritin is neither >800 mcg/litre nor the TSAT >40%)
- Iron should not generally be administered if ferritin levels are >700mcg/L or TSAT >40%.
- Blood samples should not be taken within one week of IV iron dosing.

Iron isomaltoside 1000 (Diafer) or iron hydroxide sucrose (Venofer) will be prescribed on the haemodialysis drug chart and on the PROTON medication screen, inclusive of start and stop dates (for audit purposes). The prescription for IV iron will be kept in the nursing records, signed for by the administering staff and recorded on the dialysis prescription sheet.

3.3 Home Haemodialysis (HHD) Patients

HHD patients in the UHL dialysis network have been self administering IV iron at home

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according to the same protocol as in-centre dialysis patients since 2008. These patients continue to use iron hydroxide sucrose (Venofer). There have been no recorded incidents of anaphylactic reactions. Following an MHRA alert in August 2013(5) re-emphasising that access to resuscitation facilities should be available during administration of intravenous iron, self-administration by home haemodialysis patients was temporarily suspended. However, following careful internal review and taking into account the views of other nephrology experts and the UK home haemodialysis group, it has been agreed that patients can continue to self administer IV iron at home as long as the following criteria are fulfilled and this is recorded in writing in medical notes or clinical correspondence:-

- Patients are made aware of MHRA warning and are provided with information leaflet on this topic (see appendix 1)
- Patients are offered the option of having access to and training in the use of EpiPen injection
- Patients are advised to have a carer or assistant available when administering IV iron
- Patients sign a form confirming they have received this information (as required by Cardiac, Renal and Respiratory Quality and Safety Group) (see appendix 2)
- Patients receiving training in self-administration of IV iron (see separate guideline 'Anaemia_Self Administration of Intravenous Iron by Home Haemodialysis Patients').

The alternative for HHD patients (at the discretion of the patient or his/her nephrologist) will be to have iron administered in the same way as non-dialysis CKD or PD patients or during respite sessions at haemodialysis units. Although iron isomaltoside 1000 (Monofer) is not licensed for total loading infusion in haemodialysis patients, the local view is that there is no logical reason why it cannot be given off licence in this way.

3.4 Initiating IV iron

In August 2013, the MHRA reviewed the evidence for serious reactions to IV iron and concluded that there was no evidence to support the use of an initial test dose of IV iron. This practice has now been discontinued. There is no requirement for a doctor to be in attendance when the first dose of iron is administered.

3.5 Anaphylaxis

Experience has shown that iron isomaltoside 1000 and iron carboxymaltose (Ferinject) are both associated with a very low risk of anaphylactic reactions. Any reactions are more likely to be due to rapid release of free iron. The prescribing doctor and administering nurse must confirm with the case records and with the patient that there is no history of reactions to IV iron.

Based on local experience and expert opinion, any adverse reaction to any of the preparations is a contraindication to administering any other formulation of IV iron.

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4. Monitoring and Audit criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
IV iron use in ward 10 day case	Audit of compliance with guideline/side effects	annual	tbc
Haemoglobin and iron studies on HD patients	Renal Registry return data	quarterly	James Medcalf

5. Education and training

The change in criteria for use of IV iron based on reticulocyte Hb concentration is a significant change in practice and will be widely communicated through the UHL renal network. Information on the use of reticulocyte Hb to assess for iron status is also available on the trust intranet.

6. References

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7. Keywords

Anaemia, chronic kidney disease, CKD, iron, intravenous iron.

Appendix 1

INTRAVENOUS IRON SUCROSE (VENOFER) IN HOME HAEMODIALYSIS INFORMATION FOR PATIENTS

Anaemia (a lack of red blood cells) is common in people with chronic kidney disease. It will make you feel tired and lethargic. Iron is necessary for your body to produce red blood cells. Iron tablets can be used to correct iron deficiency but in some people they do not increase the levels of iron in the body sufficiently or they cause unacceptable side effects such as diarrhoea or constipation, nausea and indigestion.

Intravenous iron sucrose (Venofer) is an alternative to iron tablets. It can be given via the dialysis machine as part of a normal haemodialysis session. Since 2008 patients on home haemodialysis have been self administering iron sucrose after completing their training.

It has always been known that patients can develop anaphylaxis (a severe-life threatening allergic reaction) to intravenous iron. The advice was that it would occur (if at all) with the first or second dose of intravenous iron. These doses are always given in hospital or a dialysis unit.

In September 2013, the Medicines Healthcare Regulatory authority (MHRA) issued a warning that anaphylaxis could occur at any time with intravenous iron and not just with the first or second dose. The MHRA recommends that intravenous iron should only be given where there are full facilities for resuscitation should an anaphylactic attack occur. This advice was based on information from all the intravenous iron products available in Europe.

The nephrologists responsible for home haemodialysis patients and home care team nurses have discussed this warning at length. In line with most other dialysis centres in England, they feel that it is safe to continue to allow self administration of intravenous iron at home by patients who are happy to do so. The potential risk has been compared with the benefits and convenience of continuing to perform self care at home rather than being dependent upon travelling to a unit to receive intravenous iron.

The risk of anaphylaxis with Venofer is extremely small (less than one in a million). It has not been experienced in our patient population either in or out of hospital. Although the risk of developing anaphylaxis is extremely small, you can be prescribed an Epipen or similar autoinjector, if you wish. These contain adrenaline for intramuscular administration which will help to control the symptoms of anaphylaxis until medical help can arrive. Both you and your dialysis partner will be told how and when to use the pen. It is advisable to have a carer or assistant available when administering IV iron.

If you do not wish to give intravenous iron at home you will be asked to attend hospital for your iron infusions at approximately three monthly intervals.

Appendix 3

Administration of intravenous iron isomaltoside 1000 (Diafer) or iron hydroxide sucrose (Venofer) on haemodialysis in hospital or satellite dialysis units (NB home haemodialysis is excluded from this section)

Competency to administer IV iron

- IV iron must be given by a registered nurse who holds an 'IV certificate' and demonstrates competency in carrying out this procedure (NMC scope of Professional Practice) and in accordance with the UHL Preparation and Administration of Intravenous Medications and Fluids to Adults, Babies, Children and Young People.
- Facilities for resuscitation must be available (except for HHD patients) including supplies of antihistamines, corticosteroids and adrenaline for parenteral use; these must be prescribed routinely for all patients prescribed IV iron on the drug chart or temporary anaphylaxis appendix so that these drugs may be administered intramuscularly or intravenously by nursing staff in the rare of event of an anaphylactic reaction
- Intravenous iron can be administered at any time during dialysis.
- 100mg of iron isomaltoside 1000 (Diafer) or iron hydroxide sucrose (Venofer) can be administered undiluted as a fast push.
- Record the patient's temperature and assess for signs of infection. Concurrent infection is a contraindication for intravenous iron. Take appropriate advice if abnormalities detected
- Pre and post iron infusion blood pressure and pulse must be monitored and recorded on the patient's communication sheet. If the patient's blood pressure is below a safe level for that patient, ultrafiltration should be switched off for 10-15 minutes, the blood pressure rechecked and, if satisfactory for that patient, then the iron can be administered.
- Wash hands with liquid soap and water; cover any visible broken skin with a waterproof dressing
- If IV iron is omitted for any reason this must be noted in the patients' communication sheet and on the drug chart.

Appendix 3(continued)

1. Equipment required

10ml leur lock syringe
1 blue (23g) needle
5mls ampoule of 0.9% sodium chloride
2 sani-cloth
Non-sterile gloves
ANTT tray
New bung

2. Procedure

- Ensure the prescription is correct and dated and signed.
- Correctly identify the patient
- Wash hands with liquid soap and water. Dry with paper towels thoroughly.
- Check all packaging for any damage and check the expiry dates prior to opening. Apply non-sterile gloves.
- With Sanicloth, clean rubber bung on iron vial for 30 seconds.
- Using a blue needle and 2ml syringe, draw up 100mg of iron
- Clean the venous bubble trap or venous IV access port with chlorhexidine 2%/ alcohol 70% wipes (Sanicloth) for 30 seconds. Allow to dry.
- Administer through bubble trap or venous IV access port as a fast push. Put a new bung on
- Discard needle and syringe in sharps bin.

Appendix 4 - Procedure for administering iron isomaltoside 1000 (Monofer) or iron carboxymaltose (Ferinject) in day case


1. Equipment required

Alcohol based hand rub
100mg and/or 500mg vials of iron according to dose
Sodium chloride 0.9% 250mls minibag
Tourniquet
1 x blue needles
1 x 10ml syringe
1 x IV additive label
1 x volumetric giving set
1 x volumetric pump

2. Procedure

- Ensure the prescription is correct, patient, dose, route, dated and signed.
- Check allergies
- Wash hands with liquid soap and water
- Check all packaging for any damage and check the expiry dates prior to opening
- Using a blue needle and 10ml syringe draw up dose of iron and add to 250ml of 0.9% sodium chloride.
- Prime giving set with resultant solution.
- Complete IV additive label, checked and signed by 2 Registered Nurses
- Using tourniquet and cannula insertion pack, site venflon, secure with tape and flush with 5mls of 0.9% sodium chloride injection
- Attach primed volumetric giving set to venflon.
- Complete documentation.
- Entering information into volumetric pump give the infusion over 15 minutes
Disconnecting the infusion
- Wash hands with liquid soap
- Apply alcohol hand rub to hands and rub until dry
- Disconnect giving set from venflon
- Remove venflon and apply pressure to puncture site using cotton wool
- Dispose of equipment correctly


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- Record patient's blood pressure and pulse, Take appropriate action if abnormalities detected
- Document on day case prescription and PROTON data base.

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Appendix 5: Day case IV iron prescription form

Ward 10

Leicester General Hospital

Addressograph

**daycase
Drug Sensitivities**

<i>Drug</i>	<i>Reaction</i>
1	
2	
3	
4	

Intravenous Iron Prescription:

Reticulocyte Hb **HB**

Previous Intravenous Iron:

Patient weight:

ESA

Iron Isomaltoside 1000 (monofér)
To be administered in
250mls Sodium Chloride 0.9% over 15minutes. (One dose).

D	Date: dd/mm/yyyy	Dose	600mg	Route	IV	Signature & Bleep No.	
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	<i>Date</i>	<i>Time</i>	<i>Sig</i>	<i>Sig 2</i>	<i>Pre</i>	<i>Post BP</i>	<i>Temp</i>	<i>Comments</i>
1			1		BP			

Sodium Chloride 0.9% Cannula Flush

D	Date: dd/mm/yyyy	Dose:	5mls	Route	IV	Signature & Bleep No.	
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	<i>Date</i>	<i>time</i>	<i>Sig 1</i>	<i>Sig 2</i>	<i>Comments</i>
1.					

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Missed Doses

<i>Date</i>	<i>Time</i>	<i>Drug Omitted</i>	<i>Reason*</i>	<i>Action</i>	<i>Signature</i>
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Signature:

NJH/PS Aug 2016


Updates	Sue Sharman/Pete Topham(Dec 2003) Suzy Pearce/Gill Hartley (March 2005) Updated Graham Warwick (Feb 2014) Updated J Burton/T Mushambi (Oct 2016)	Title: Renal specialist nurse/Renal Consultant Consultant Nephrologist Consultant nephrologist/Renal SpR
Ratified by: Date:	HD Consultants and Matrons	
Review date:		

REVIEW RECORD

DATE	ISSUE NUMBER	REVIEWED BY	DESCRIPTION OF CHANGES (IF ANY)
March 2005	2	G Warwick	
	2	G Hartley	
	2	J Price	
Dec 2006	3	P Topham	Inclusion of maintenance IV iron for HD pts.
Feb 2014	4	M Quashie-Howard/G Warwick	Change of the parameters for haemoglobin. Merging of two iron protocols for different products Removal of test dose for IV iron and updated procedure for self administration by home HD patients Emphasis on use of oral iron for CKD and PD patients

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October 2016	5	J Burton T Mushambi Helen Riddleston Maria Martinez	<ol style="list-style-type: none"> 1. Change of iv iron preparation to Monofer for outpatients and Diafer for in centre haemodialysis patients 2. Change in the test used to assess for iron deficiency from ferritin/TSR to reticulocyte haemoglobin. 3. Inclusion of the contraindication to any other preparation of iv iron if an adverse reactions with one formulation develops 4. day case iv iron prescription
Jan 2019	5	J Burton	No changes

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