

## Iron Infusions & Extravasations

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Reference Number: RDF2429-24

Date of Response: 16/04/24

Further to your Freedom of Information Act request, please find the Trust's response(s) below:

*To sum up. I am looking at a 10-year period (2013-2023). I am looking to discover how many times IV Iron is administered, how many times an extravasation injury occurs and lastly what information patients are given prior to the transfusion and what policies are in place.*

### Question 1

*How many times has IV Iron been administered each year in the years 2013-2023 within the organisation. For clarity and by way of example, how many times in 2013 was administered (given intravenously) - the same for each of the years thereafter until 2023.*

Year	count
2021	8
2024	8
2022	19
2023	22

### Question 2

*How many iron extravasations have been reported within your organisation within the 10-year (complete years) period 2013-2023. For clarity, I am asking how many extravasations reports were made, involving iron infusions, between 2013-2023, complete years, January to December in each of those years. I am aware that there is no specific coding for Iron Extravasation. However, the incident forms for each year can be reviewed and if it does not include an IV iron infusion can be excluded - this should take a few seconds per incident form.*

Year	count
2018	0
2019	0
2020	0
2021	0
2022	0
2023	*<5
2024	0

\*<5

Please note that in accordance with Section 40 (2) where activity is 5 or less than 5, the Trust is unable to provide the exact information. We consider the data exempt on the following grounds:

The Trust considers that disclosure of the information risks identifying individuals. The reason for this is that the number of patients for which this applies is very low. This and the fact that the data requested relates to the RDUH Health NHS Trust only and therefore relates to patients treated in a specific location (rather than covering a larger geographical area), increases the risk of identification or self-identification. The Trust's view is that s.40(2) is applicable because disclosure of information which could lead to a patient being identified would be a breach of the patient's rights under the Data Protection Act Data Protection Principles set out in Schedule 1 of the GDPR, namely Principle 1.

*Question 3*

*Are patients given any information leaflets about iron infusions prior to infusion? May I have a copy?*

*Question 4*

*Do you have an iron infusion policy - May I kindly have a copy?*

Please find attached the following in answer to questions 3 and 4.

Patient information can be found on page 12 onwards.

- Ferric-Desferrioxamine-Community-Clinical-guideline-updated-September-2023 (1) \_Redacted

Please note. Certain contact details and staff names have been redacted under Section 40 of the Freedom of Information Act.

The Trust does not release the names of staff and emails under Section 40 (2) of the Freedom of Information Act 2000 Personal Information, where disclosure may contravene the Data Protection Act 2018 and therefore applies an exemption under Section 40 (2) - Personal Information of the Freedom of Information Act 2000 and Section 10 of the Data Protection Act 2018.

## Clinical Guideline for The Administration of Parenteral Iron Infusions (Ferric Derisomaltose) in Community Ambulatory & Day Treatment Units (DTU)

### SUMMARY

This guideline outlines the process to support the appropriate administration of Iron infusions in Community Hospitals across the Royal Devon University Healthcare Trust.

Parenteral Iron is indicated for patients with iron deficiency anaemia when oral Iron therapy is unsuccessful or not tolerated.

As per these guidelines intravenous iron is only to be administered as an infusion and not as an intravenous bolus injection.

### KEY POINTS

#### Referrals

Patients appropriate for iron infusions in Community Hospitals are identified either through:

- General Practitioner (GP) direct request- via emailing referral form
- Secondary Care clinician request- via EPIC order
- Ambulatory/DTU Team discussion with GP after review of a blood transfusion request

Information around Community Hospital Ambulatory/DTU are available on [HUB](#). For further information please contact;

Eastern locality- Community Ambulatory- [REDACTED]

Northern locality- Day Treatment Units- [REDACTED]

Facilities for cardiopulmonary resuscitation must be available.

#### Prescribing

Ferric Derisomaltose (**previously known as Monofer**) is the only parenteral iron product to be prescribed in Community Hospitals as per recommendations in the North and East Devon Formulary

<https://northeast.devonformularyguidance.nhs.uk/formulary/chapters/9-blood-and-nutrition/9-1-anaemias/9-1-1-iron-deficiency-anaemias>

The Ferric Derisomaltose dose prescribed is based on the individual patient's needs including weight and iron deficit. Secondary care prescriptions must be placed using a 'signed and held for ambulatory' order within EPIC. Primary care referrals will be prescribed locally.

#### Supplies

Parenteral iron supplies are dispensed on a named patient basis by the RDUH Pharmacy department.

### Administration

All referrals will be triaged for community suitability, as per risk factors and drug contraindications.

**High risk referrals and those with previous IV iron allergy and anaphylaxis history will be assessed at triage and referred onto the acute setting.**

Patient observations should be stable prior to administration.

The patient should be afebrile and not acutely unwell.

All patients should be closely monitored during the infusion for signs of hypersensitivity and extravasation during and for at least 30 minutes after every administration of Ferric Derisomaltose and observations taken as per page 6 of this guideline

### Follow up

It is recommended that referring clinicians repeat a full blood count, ferritin and mean corpuscular volume (MCV) at 6 weeks post transfusion to review the efficacy of the iron transfusion.

### Audit

Activity of iron transfusions in Community Hospitals will be audited annually.

## CONTENTS

1.	INTRODUCTION / BACKGROUND	3
2.	MAIN BODY OF GUIDELINE	4
3.	MONITORING COMPLIANCE WITH THIS GUIDELINE	6
4.	ASSOCIATED CLINICAL GUIDELINES/ POLICIES/ PROCEDURES	7
5.	PUBLICATION DETAILS	7
Appendix 1	Ferric Derisomaltose dose calculator	10
Appendix 2.	Patient Information Leaflet	11
Appendix 3.	Community Ferric Derisomaltose infusion- patient facing final checks	15
Appendix 4.	Community pathway for management of hypersensitivity in Ferric Derisomaltose	16
Appendix 5.	Anaphylaxis algorithm	17

## **1. INTRODUCTION / BACKGROUND**

Anaemia occurs when red blood cells (RBC) production is decreased, RBC destruction is accelerated, or RBCs are lost due to bleeding. The most common type of anaemia is Iron Deficiency Anaemia, with a prevalence of 2-5% in adult men and post-menopausal women.

Parenteral Iron is indicated for patients with Iron deficiency anaemia when oral Iron therapy is unsuccessful or not tolerated.

Patients with Iron Deficient Anaemia and a functioning bone marrow need iron rather than blood. An average infusion of intravenous iron is 1,000mg of iron; this is equivalent to the amount of iron in 4 units of packed red cells

The first treatment choice is to use oral iron but intravenous iron should be considered for patients:

Who cannot tolerate or are unable to take oral iron

- For whom oral iron has been ineffective
- In whom oral iron is likely to be ineffective e.g.in patients with chronic renal disease or anaemia due to chronic disease or inflammation.
- Where there is not sufficient time for oral iron to work, e.g. pre-operatively

Intravenous iron will improve the haemoglobin in iron deficient patients in 7 to 14 days. Blood transfusion may be needed to relieve symptoms of anaemia such as angina, intermittent claudication, shortness of breath that require correcting quickly. In these patients often a single unit of blood can overcome the acute symptoms and this can be backed up by an iron infusion at the same time.

Parenteral iron infusions can be administered for Ambulatory/DTU. These Community sites have been risk assessed and have facilities for the management of anaphylaxis and cardiopulmonary resuscitation and have staff competent to administer intravenous infusions and manage emergency situations.

As per these guidelines intravenous iron is only to be administered as an infusion and not as an intravenous bolus injection.

## 2. MAIN BODY OF GUIDELINE

### Referrals

Patients appropriate for iron infusions in Community Hospitals are identified either through:

- General Practitioner (GP) direct request- **via emailing referral form**
- Secondary Care clinician request- **via EPIC order**
- Ambulatory/DTU Team discussion with GP after review of a blood transfusion request

Information around Community Hospital Ambulatory/DTU are available on [REDACTED]

For further information please contact;

Eastern locality- Community Ambulatory- [REDACTED]

Northern locality- Day Treatment Units- [REDACTED]

**Please note the Community Ambulatory/DTU service operates Monday-Friday.**

**Serious hypersensitivity reactions, including life-threatening and fatal anaphylactic reactions, have been reported in patients receiving intravenous iron therefore facilities for cardiopulmonary resuscitation including oxygen and suction must be available at the Community Hospital and access to anaphylaxis equipment including adrenaline should be available in the treatment area.**

**Staff administering intravenous iron infusions must be competent and up to date with anaphylaxis, resuscitation and intravenous drug administration training.**

### Prescribing

The F2 or NMP prescriber does not have to be present in the Community Hospital when the infusion is taking place but does need to be accountable for appropriate prescribing and safe administration.

Ferric Derisomaltose is the **only** parenteral iron product to be prescribed as per recommendations in the Joint North and East Devon Formulary.

<https://northeast.devonformularyguidance.nhs.uk/formulary/chapters/9-blood-and-nutrition/9-1-anaemias/9-1-1-iron-deficiency-anaemias>

**Contra indications to Ferric Derisomaltose as per the Summary of Product**

**Characteristics (SPC)**

[Ferric Derisomaltose 100mg/ml solution for injection/infusion - Summary of Product](#)

[Characteristics \(SPC\) - \(eMC\)](#)

Include:

- Non-iron deficiency anaemia.
- Iron overload or disturbances in utilisation of iron.
- Hypersensitivity to any of the ingredients.
- Patients with a history of severe asthma, allergic eczema or other atopic allergy.
- Decompensated liver cirrhosis and hepatitis.
- Rheumatoid arthritis with symptoms or signs of active inflammation
- It is not recommended to administer oral iron until 5 days after the last iron infusion

The risk of hypersensitivity is increased in patients with known allergies, immune or inflammatory conditions (e.g. Systemic lupus erythematosus (SLE) and rheumatoid arthritis); or those with 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 risks.

The Ferric Derisomaltose dose prescribed by the F2 or NMP should be based on the individual patient's needs including weight and iron deficit.

The North and East Devon Formulary and Referral (2022) guidance state that the 1<sup>st</sup> choice in IV preparation for hospital administration is Ferric Derisomaltose. Ferric Derisomaltose should be prescribed according to the manufacture's guidelines. The prescription should be based on the iron need and this is worked out in 1 of 2 ways. In a patient who is anaemic, a dose of up to 20mg/kg of Ferric Derisomaltose can be given in one infusion. For those who are iron deficient but not anaemic the recommended dose is up to 10mg/kg.

**Iron Isomaltoside ADULT Dosing Guidance**

Dose of Iron (calculate if weight <50 kg)												
Weight (kg)	<50	50-54.9	55-59.9	60-64.9	65-69.9	70-74.9	75-79.9	80-84.9	85-89.9	90-94.9	95-95.9	>100
Anaemic	20 mg/kg g	1 g	1.1 g	1.2 g	1.3 g	1.4 g	1.5 g	1.6 g	1.7 g	1.8 g	1.9 g	2 g
Non-anaemic	10 mg/kg g	500 mg		600 mg		700 mg		800 mg		900 mg		1 g

Alternatively dose can be calculated using 'monofer calculator' on Hub; recommended for patients BMI>30 kg/m<sup>2</sup>.

The Ferric Derisomaltose calculator is used (Appendix 1)

If the patient -

- Is under 50Kg in weight
- Is under 160cm in height
- Has a BMI above 30


It is recommended that doses are prescribed in whole units e.g. 1200mg not 1250mg.

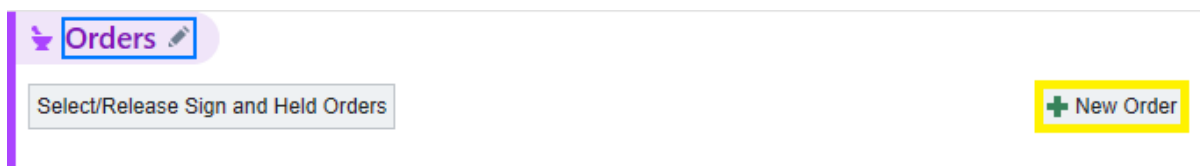
All prescriptions are checked and verified for dosage suitability and dispensed by pharmacy.

### Prescribing on EPIC via “orders for admission”

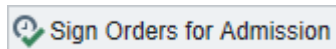
The individual prescription should be placed electronically via epic by placing an order for admission.

**Orders for Admission** can be accessed from an ‘Orders Only’ encounter via the ‘Orders for Admission’ tab.

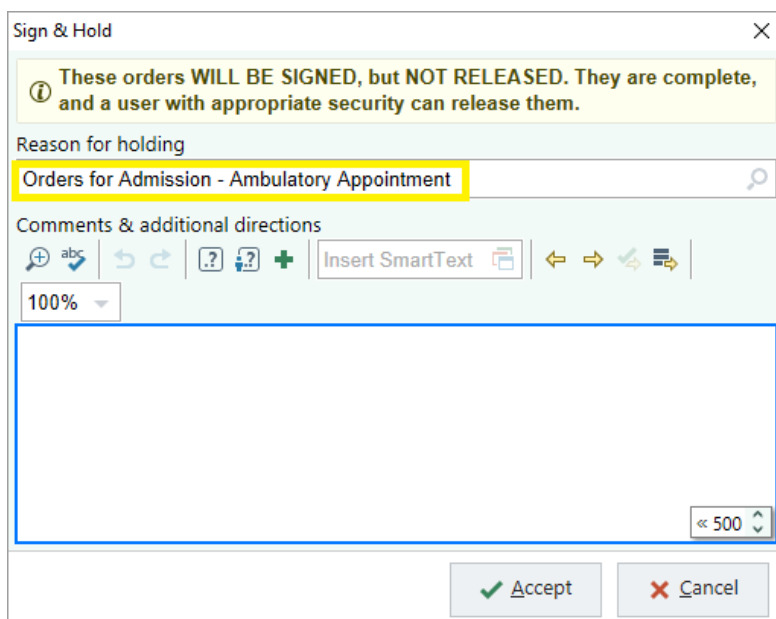
From clinic appointments this is available from the More Activities  menu in the top right of the workspace. You can add individual medication orders using the ‘Orders’ section and selecting ‘New Order’



When you’ve completed your order(s), click **Sign Orders For Admission**.



On the popup, change the hold reason to ‘Orders for Admission – Ambulatory Appointment’.



All prescriptions should include/consider:

- Patients name and weight (Height if under 50kg in weight)
- Allergy status



- Ferric Derisomaltose Dose written in mg
- Route of administration
- Dilution - Ferric Derisomaltose must only be diluted in 0.9% sodium chloride (recommended 100mls)
- Infusion duration

**Doses should be infused over at least 30minutes. If there are precautions for use identified doses should be given over 1 hour as shown in Community Ferric Derisomaltose pathway (Appendix 3).**

### **Supplies**

Parenteral iron supplies should be dispensed on a named patient basis by the RDUH  
Four 500mg vials are in stock for use within the transfusion service at Sidmouth and Tiverton hospital these are only to be used in a scenario where a patient needs to attend for an iron infusion urgently and there isn't enough time to pre-prescribe. All doses will be verified by pharmacy prior to administration.

### **Administration**

On the day of the Ferric Derisomaltose infusion, patient observations should be at a stable baseline to rule out possibility of sepsis.

Prescription checked against up to date weight and height.

Patients should be verbally informed of the risks of Ferric Derisomaltose infusions, including risk of extravasation and recognition of any adverse reactions. and given a patient information leaflet (**Appendix 2**).

Patient's verbal consent should be documented.

Release signed and held prescription within 'charting tab' of patient EPIC notes.

 [RD&E Boots Pharmacy](#)  01392 408437  
[→ Signed & Held](#)  [Providers](#)  [Current Interactions](#)

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Ferric Derisomaltose should only be administered through an appropriate vascular access device and delivered via an IV pump. The IV site and the Visual Infusion Phlebitis /Central Line Infection Prevention (VIP/CLIP) score should be recorded and site observed for any signs of extravasation (leakage of drug into the tissue). The cannula should be flushed pre and post transfusion with 0.9% sodium chloride.

All patients should be closely monitored for signs of hypersensitivity during and for at least 30 minutes after every administration of Ferric Derisomaltose.

Baseline observations and early warning score should be completed prior to the infusion being commenced and again on completion.

On completion of infusion patients should then be observed for adverse effects for at least a further 30 minutes before being discharged and information leaflet given (**Appendix 2**).

## **Main Complications**

### **Extravasation**

Extravasation of all forms of IV iron therapy may result in permanent skin pigmentation and skin irritation. Iron should therefore only be transfused via larger visible veins and if any symptoms or signs of extravasation are suspected the infusion should be discontinued immediately and the GP/F2 informed. Treatment is dependent on the severity of the extravasation and should be determined before removal of the cannula; advice may be sought from the RDUH Trust IV Policy and the RDUH Pharmacy Department. All incidents of extravasation should be documented in the patient's notes and a datix incident form completed (**Appendix 3**).

### **Mild hypersensitive reactions (Fishbane)**

Displays any of the following-

- Itching
- Flushing
- Hypertension
- Back/joint pain
- Minor chest tightness

**Should Fishbane reactions occur please follow hypersensitivity pathway as shown in Appendix 4.**

### **Anaphylaxis (Appendix 5)**

- **This is an emergency**
- Stop infusion
- Call for help
- Get adrenaline 1:1000 injection
- Use ABC approach
- Give 0.5ml of 1:1000 adrenaline IM

In the event of the patient suffering an adverse drug reaction, treatment should be stopped immediately and appropriate management initiated. The F2/GP and the nurse in charge must be informed as soon as possible after the patient's needs have been addressed. The incident must be recorded in the patient record, including updating allergy status, indicating the actions taken and highlighting the medication which prompted the adverse reaction. It should be reported on Datix in accordance with the Trusts Incident reporting policy. A Medicines and Healthcare products Regulatory Agency (MHRA) 'Yellowcard' should be completed, details are found in the British National Formulary (BNF) and online at: <https://yellowcard.mhra.gov.uk/>

**Follow up**

Referring clinicians are advised to repeat full blood count, ferritin and MCV at 6 weeks post transfusion to review the efficacy of the iron transfusion.

**3. MONITORING COMPLIANCE WITH THIS GUIDELINE**

Iron infusions carried out in Community Hospital will be audited annually. Results will be shared with General Practice, Community Hospital staff and the Hospital Transfusion Team

**4. ASSOCIATED CLINICAL GUIDELINES/ POLICIES/ PROCEDURES/ REFERENCES**

Medusa (Injectable medicines guide) – Available on the RDUH Hub –

██████████

MHRA Drug Safety Update. Volume 6; Issue 1 August 2013. Intravenous iron and serious hypersensitivity reactions; new strengthened recommendations to manage and minimise risk.

National Institute for Health and Care Excellence Blood transfusion Guidelines (Nov 2015)

RCN Iron Deficiency and Anaemia in Adults (June 2015) RCN guidance for nursing staff

Resuscitation Council (UK) [www.resus.org.uk](http://www.resus.org.uk)

**5. PUBLICATION DETAILS**

<b>Author of Clinical Guideline</b>	██████████ <i>Transfusion Practitioner.</i> ██████████ <i>Patient Blood Manager</i>  <i>Re-written September 2023-</i>  ██████████ <i>Transfusion Practitioner</i> ██████████ <i>Business Manger</i>
<b>Division/ Department responsible for Clinical Guideline</b>	<i>Community Specialist Services</i>
<b>Contact details</b>	██
<b>Version number</b>	4

<b>Replaces version number</b>	3
<b>Date written</b>	2/02/2017 updated Oct 2018 Re-written Sept 2023
<b>Approving body and date approved</b>	Patient Blood Management Group 26/01/2017 Medicine Management Group for info 08/02/2017 CAG 17/05/2017 Community Pharmacy Review 24/10/2023 Hospital Transfusion Team 02/11/2023 Divisional governance group-30/11/2023
<b>Review date</b>	(3-6 months prior to expiry date)
<b>Expiry date</b>	30/11/2028
<b>Date document becomes live</b>	10/08/2017

## Appendix 1

### Ferric Derisomaltose (iron (III) isomaltoside 1000) dosing calculator

Use the following link to access the calculator

		Range permitted
Sex	Female	Male, Female
Height	cm	150 - 250 cm
Weight	kg	30 - 400 kg
Ideal body weight	kg	
Weight used	kg	

Current haemoglobin	g/L	30 - 150 g/L
Target haemoglobin	g/L	100 - 150 g/L

Total dose required	mg Ferric Derisomaltose

Dose for first infusion	mg Ferric Derisomaltose
Minimum time for first infusion	minutes

Dose for second infusion	mg Ferric Derisomaltose
Minimum time for second infusion	minutes

[https://hub.exe.nhs.uk/search/?q=Ferric Derisomaltose+calculator](https://hub.exe.nhs.uk/search/?q=Ferric+Derisomaltose+calculator)



## **Appendix 2**

### **Patient Information Leaflet P-1&2**

## What is FDI?

FDI is a dark brown liquid containing iron. It is used for treating iron deficiency when oral iron preparations are ineffective or cannot be used, or when there is a need to deliver iron rapidly.



## Iron facts

- The human body contains 3–4 grams of iron, approximately two-thirds of this iron is found in the red blood cells
- Iron is needed to produce haemoglobin, the protein that transports oxygen around the body in red blood cells, and myoglobin, a similar protein that is found inside muscle tissue
- Iron is found in many enzymes, such as those that aid energy production. It is also used by the body for assisting the immune system
- Each day, an adult male requires around 11 milligrams (mg) of iron and an adult woman requires around 25 mg. This daily requirement usually comes from dietary sources

Sources: Stein J. et al. *Nutr Rev Gastroenterol Hepatol*. 2010;7:599–610.  
WHO/FAO. Vitamin and mineral requirements in human nutrition.  
World Health Organization; 2004:1–341.

### Reporting of side effects

Ferric derisomaltose

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

FDI, ferric derisomaltose.

If you need information or advice, please contact your nurse or doctor, who can also contact:

Pharmacosmos UK Ltd  
The White Building  
33 Kings Road  
Reading  
RG1 3AR  
T: +44 1844 269 007  
F: +44 1844 269 005  
E: [info@pharmacosmos.co.uk](mailto:info@pharmacosmos.co.uk)  
[www.pharmacosmos.co.uk](http://www.pharmacosmos.co.uk)

UK-FDI-0323-00004  
Date of preparation: March 2023



Treating iron deficiency  
with ferric derisomaltose  
Pharmacosmos 100 mg/ml  
solution for injection/infusion

## Patient information



For more information on iron and how to prepare for your infusion, watch our patient video by scanning the QR code



### Why am I being treated with FDI?

FDI (which is short for ferric derisomalitose) is used for treating iron deficiency. Your doctor will have chosen this treatment because you need to correct the iron levels in your body.

### Why do I need iron?

Iron plays a key role in many processes, especially in facilitating the formation of red blood cells and enabling them to carry oxygen around the body. A lack of iron can make us feel tired, dizzy, irritable, unable to sleep and lead to dry skin or hair loss.

### Before receiving treatment

Treatment with FDI does not require any preparation from your side. Have your usual meals on the day and make sure you are well-hydrated. Continue taking all your usual medications, but stop any iron tablets at least a day before your appointment. Wear loose, comfortable clothes and a short-sleeved shirt. You can also bring along a book, or something to watch. We advise you to go through your full medical history with your doctor. Please note that this leaflet does not replace the Patient Information Leaflet, which your doctor or nurse can provide you with.



### Administration

FDI is an intravenous iron treatment that is administered directly into a vein. This means the iron is delivered into your bloodstream via a drip, or you might receive it from a slow injection, all while being monitored by a nurse. The iron doesn't hurt, but you may feel a cold sensation in your arm.

### Are there any side effects during treatment?

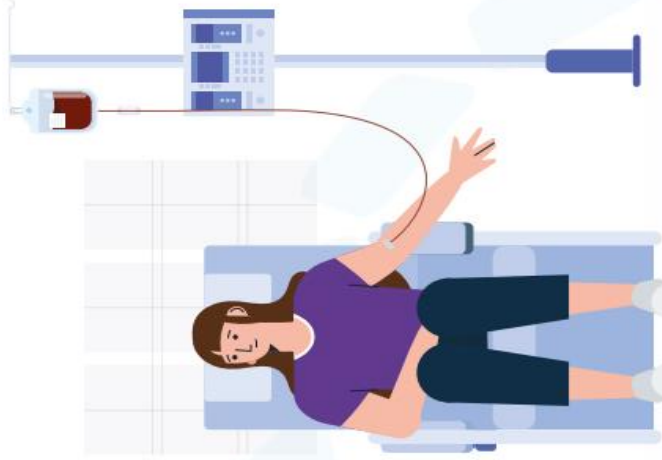
Like all medicines, FDI can cause side effects, although not everybody gets them. Your doctor will discuss all possible side effects with you before starting treatment. For all intravenous iron treatments administered directly into your arm, there is a low risk that you may experience a severe hypersensitivity reaction. Symptoms can include breathing difficulty, dizziness and swelling in the mouth. Your doctor or nurse will be monitoring you closely to make sure your body is responding well to the treatment. There is a risk (uncommon) that iron could leak and cause a stain to your skin which may be permanent. If you experience pain, discomfort, or notice leaking around the treatment site, please let your doctor or nurse know immediately.

A few days after treatment, you might experience headache, mild fever or joint pain – these symptoms usually settle on their own. Tell your doctor or nurse if you experience any symptoms during treatment.

The procedure will be stopped immediately – they'll take care of you, and let you know if it's possible to restart. You can find more information on possible side effects in the Patient Information Leaflet provided with your medicine.

### How long will the infusion take?

It will take around 30 minutes to receive your iron. Your nurse or doctor will keep you for an additional 30 minutes afterwards to ensure you're well before going home.



### What happens after treatment?

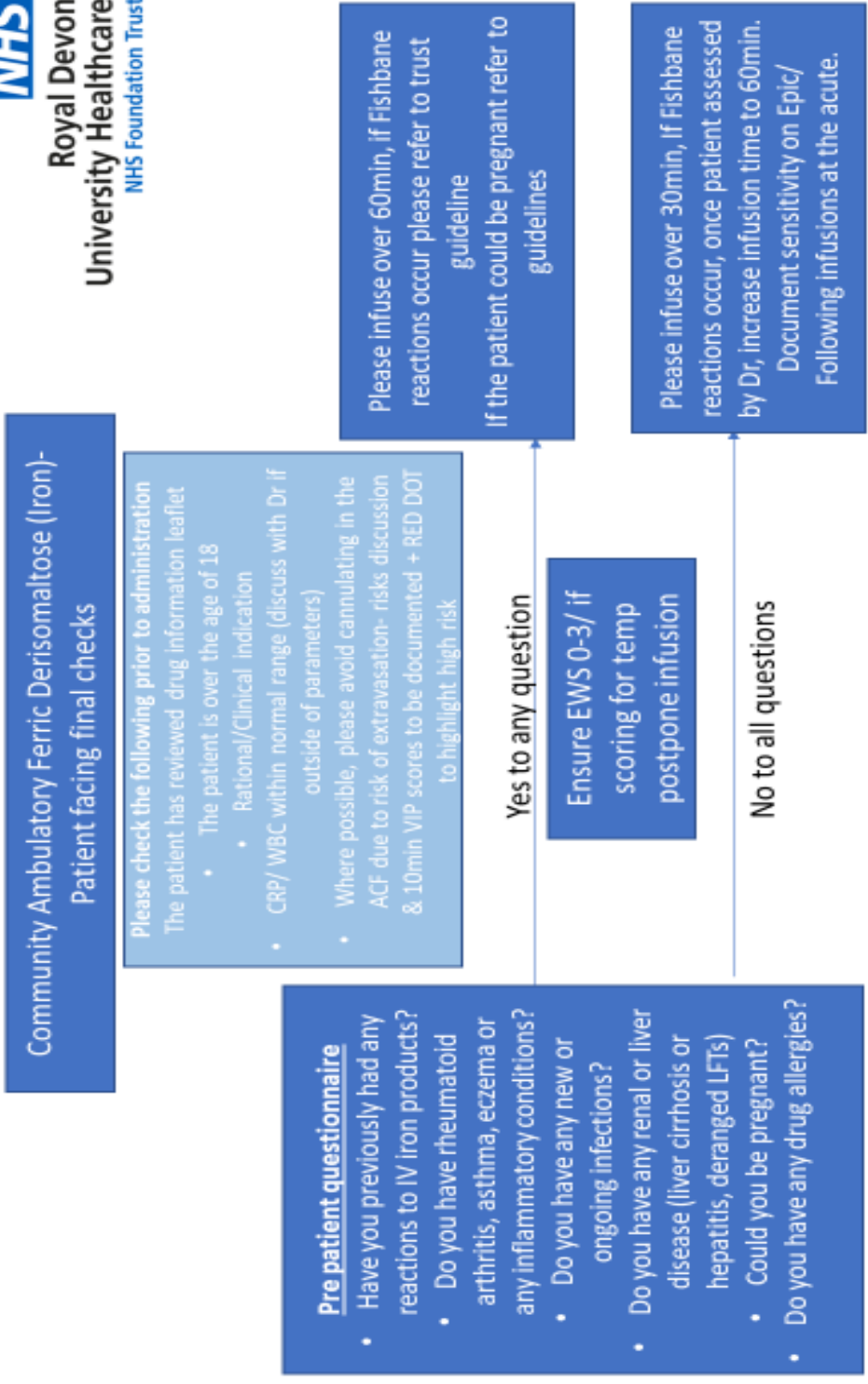
A new blood sample will usually be taken some weeks or months after the treatment to determine if your body's iron stores are fully corrected. Depending on your weight and how iron deficient you are, you may only need one treatment to restore your body's iron stores – unless you have ongoing issues that affect your iron levels.

### Are you taking iron tablets?

If you are taking iron tablets on a daily basis, it is recommended that you discuss this with your doctor, as you will likely need to stop taking them for a while after your treatment with FDI.



Appendix 3

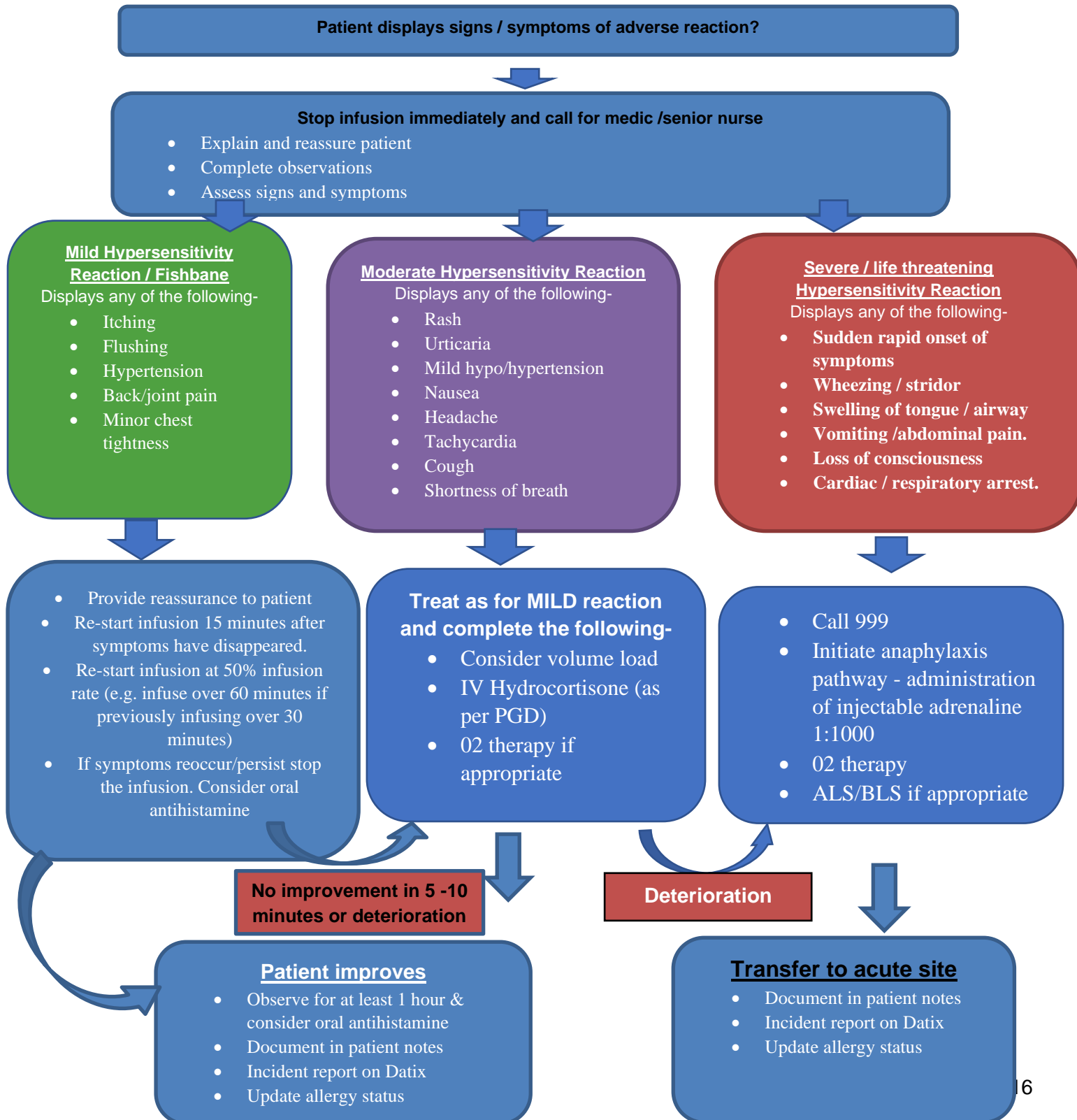


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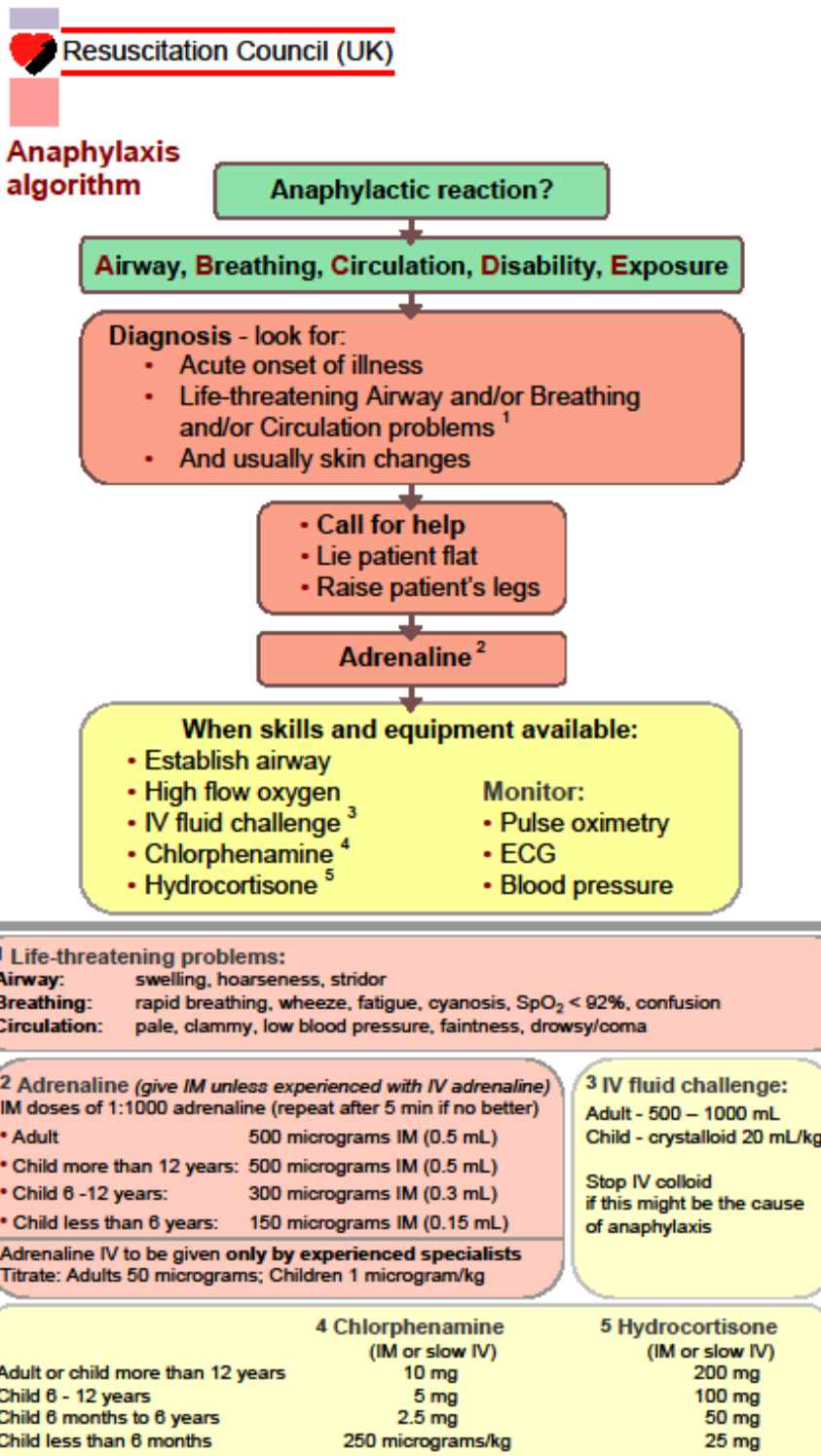
**Appendix 4**

**Pathway for the management of hypersensitivity reactions to intravenous Ferric Derisomaltose for patients in the community ambulatory / day case setting**

Each patient should be observed for signs and symptoms of hypersensitivity reactions during and for at least 30 minutes following each parenteral iron infusion.



Appendix 5



See also: ► [Anaphylactic reactions – Initial treatment](#)