Royal Free London
NHS Foundation Trust

Anaemia pathway and IV Iron infusion in pregnancy

March 2023

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Validation Grid	
Version	V3.0
Title	Anaemia pathway and IV Iron infusion in pregnancy
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Lead Business Unit	Maternity, BHBU
Target audience	Obstetrics staff, Midwives
Commissioning body (e.g. Directorate/CPG)	Women and Children's
Stakeholders consulted	Obstetrics team cross site
Clinical Practice / Advanced Practice	Clinical Practice
Associated Policies / Documents	Extravasation policy Trust IV administration policy
Guideline Replacement	Intravenous Iron Infusion (Monofer) in Pregnancy. 2022 Intravenous Iron Infusion (Monofer) in Pregnancy. 2018
Issue date	March 2023
Ratified by	The Women's Services Guidelines Group (WSGG) on behalf of the Women and Children's Division
Date of ratification	WSGG: March 2022 DTC: June 2022
Date for review	March 2023
Applicable to RFH, BH, CFH , GCS	All sites
Significant change to practice	New Guideline for Royal Free Hospital site
Implementation plan (including dissemination plan and audit plan if significant change to practice)	Dissemination of the guideline freenet Monitoring via the annual audit cycle
Key words	Monofer

Version control				
Version	**Date**	**Author**	**Status**	**Comment**
1	April 2018	Rezan Kadir	Superseded	New harmonised guideline
2	May 2022	Ariadne L'Heveder	Superseded	Review
3	January 2023	Ariadne L'Heveder	Current	Brief update

Contents

Royal Free London equality & diversity statement

"The Royal Free London NHS Foundation Trust is committed to creating a positive culture of respect for all individuals, including job applicants, employees, patients, their families and carers as well as community partners. The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability (including HIV status), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. It is also intended to use the Human Rights Act 1998 to treat fairly and value equality of opportunity regardless of socio-economic status, domestic circumstances, employment status, political affiliation or trade union membership, and to promote positive practice and value the diversity of all individuals and communities.

This document forms part of the Trusts commitment, you are responsible for ensuring that the Trust's policies, procedures and obligation in respect of promoting equality and diversity are adhered to in relation to both staff and service delivery."

1. Aim of guideline and background

The purpose of this guideline is to provide advice regarding the investigation and management of iron deficiency anaemia in pregnancy including the safe prescribing and administration of Monofer®.
Iron deficiency anaemia is very common in pregnancy with the prevalence in the UK thought to be up to 46%. It is an important cause of poor health outcomes in the mother, fetus and infant, including increased risk of postpartum haemorrhage, postnatal depression as well as associations with preterm birth and low birth weight.

2. Investigation and management of anaemia

The investigation and management of anaemia is outlined in **appendix 1**. Complex cases such should be discussed with a consultant with an interest in obstetric medicine. Monofer should **NOT** be administered at less than 34+0 weeks' gestation in exceptional circumstances following discussion with a consultant, due to the risk, albeit very small, of an adverse reaction and bradycardia resulting in early iatrogenic delivery. In view of this risk, infusions taking place before 34+0 should take place at Barnet Hospital.

3. Dosage and frequency of use

Please refer to the summary of product characteristics (SPC available at www.medicines.org.uk) for full prescribing information on Monofer.

The dose of Monofer is expressed in milligrams (mg) of elemental iron. The cumulative dose of iron using Monofer is determined based on the patient's body weight and Hb level and must not be exceeded. It is the prescriber's responsibility to ensure this is done correctly. The following table should be used to determine the cumulative iron dose required:

Hb (g/L)	Patients with booking body weight 50kg to ≤75kg	Patients with booking body weight > 75kg
≥90	1000mg	1500mg
<90	1500mg	2000mg

Note:

- Actual booking body weight should be used for patients with body mass index (BMI) <30
- Ideal body weight should be used for obese patients (BMI ≥30) (**see appendix 2**) at booking
- Individualised dosing using the Ganzoni formula (**see appendix 2**) is recommended for patients weighing <50kg at booking
- Maximum dose is 20mg/kg in a single infusion. If cumulative iron dose exceeds 20mg/kg it must be delivered in divided infusions at least 1 week apart. Alternatively, Hb can be repeated 2 weeks post 20mg/kg maximum infusion and further infusion arranged only if anaemia persists.
  See Appendix 2. for Dose Calculation Flow chart

Referral for iron infusion

- A decision for iron infusion should be made using the "Antenatal anaemia optimisation pathway" – **appendix 1**. Infusions should be used in the following circumstances:
    - Oral iron not tolerated after education regarding absorption, changing iron preparation and type, reducing dosing to alternate days
    - Quick iron replacement required (ie within less than 4 weeks)
    - Oral iron not adequately elevating Hb
- Once decision for antenatal iron infusion has been made by an obstetrician, a phone call to Maternity Day Assessment Unit (MDU) should be made to arrange date and time of infusion. The infusion will take place on labour ward.
- Monofer should be prescribed on EPR using the Monofer Maternity Prescribing Plan which includes all ancillary medications. Labour ward need to be informed of when patients are due to receive their infusion and to liaise with pharmacy. The maternity or weekend pharmacist will review and supply the prescription prior to the patient's appointment.
- Monofer is only licensed for use in the second and third trimester
- Monofer should only be used in pregnancy if there are clearly defined benefits

- Patients should be provided with an information sheet at time of referral
    - Basic information about iron infusion & what to expect
    - Appointment date and time
    - Directions to Labour ward
    - Contact information
    - Instruction to call labour ward on morning of planned IV iron infusion to confirm availability. (If labour ward very busy the appointment may need to be rescheduled)

4. Patient monitoring before, during and after infusion

- A set of observations (blood pressure (BP), pulse rate (HR), respiratory rate (RR), saturations (SaO2%), temperature (T)) and MEWS (Maternity Early Warning Signs) score should be recorded prior to infusion**.**
- If the patient has any signs or symptoms of infection inform an obstetrician. They will decide whether it is appropriate to delay the infusion until the infection has resolved.
- Relevant past medical history and allergies should have been reviewed by the doctor at time of dose calculation/prescription (see **Appendix 2**) and should be confirmed by the midwife administering the infusion.

Fetal heart monitoring

- The use of Monofer is associated with fetal heart rate abnormalities, these are usually transient and will recover on stopping the infusion. Continuous fetal heart rate monitoring should be commenced before the infusion, continued during the infusion and for 30 minutes after the infusion has completed
- **During infusion** observations should be monitored **every 15 minutes** (BP, HR, RR, SaO2, MEWS score).
- **Following infusion** observations should be monitored **every 15 minutes for 30 minutes** (BP, HR, RR, SaO2, MEWS score).

- If patient feels unwell, observations become unstable, or you suspect a hypersensitivity reaction the infusion should be stopped. Most reactions are self-limiting, and infusion can be restarted and delivered more slowly. Alert an obstetrician and or an anaesthetist.
- Anaphylactic reactions are characterised by sudden onset respiratory and or cardiovascular collapse +/- rashes/itching/swelling within the first few minutes of infusion. They can be fatal. The infusion must be stopped and disconnected immediately.
  Appropriate resuscitation equipment and skilled help must be readily available (crash call 2222 via switchboard).
  Drugs required for management of suspected anaphylaxis are available in the clinical area in a pre-prepared 'ANAPHYLAXIS KIT'

See Appendix 3 for reaction management algorithm and anaphylaxis protocol

5. Method of administration

- Doses should be diluted in 100ml sodium chloride 0.9% (although volumes up to 500ml are acceptable where appropriate) and administered by IV infusion. Only sodium chloride 0.9% should be used for dilution and flushing of cannula pre and post infusion.
- Doses up to 1000mg to be administered over 15 minutes.
- Doses above 1000mg to be administered over 30 minutes.
- Infusion time should be increased beyond 30 minutes to 1 hour if a hypersensitivity reaction is anticipated
- No other therapeutic agents should be added.

Storage and handling

- Inspect vials for sediment and damage before use and only use if sediment free.
- Store vials at room temperature.
- Each vial is intended for single use. Any unused product should be discarded.

6. Contraindications, cautions, and side effects

Contraindications to iron infusion

- Previous history of allergy to iron preparations or true iron allergy
- Iron overload or disturbances of iron utilisation (e.g. haemochromatosis)
- Hypersensitivity to the active substance
- First trimester of pregnancy
- Non-iron deficiency anaemia (e.g. haemolytic anaemia)
- Decompensated liver cirrhosis and hepatitis

Cautions

- Active infection
- Symptomatic asthma, eczema, atopy
- Rheumatoid arthritis/SLE

If any of the above conditions are present the patient is at greater risk of hypersensitivity reactions.

Side effects and reactions

- Immediate Action
    - Hypersensitivity (see **Appendix 3** for reaction management algorithm)
    - Anaphylaxis (see **Appendix 3** for reaction management algorithm)
    - Extravasation
        - Stop infusion, aspirate residual medicine via cannula, elevate limb
        - Can contact doctor and Medicines Advice Service (ext. 33114)
        - Tissue damage is rare though permanent skin staining can occur.
- Delayed (hours to days post infusion)

    Uncommon (≥1:1000 to <1:100)
        - Flushing, rash
        - Cramps
        - GI symptoms (nausea, vomiting, abdominal pain, constipation)
        - Blurred vision, numbness
        - Difficulty breathing
        - Hypophosphatemia- usually transient and asymptomatic but advise patients to seek help if suffer excessive fatigue, nausea, dizziness leg cramps

    Rare (≥1:10000 to <1:1000)
        - Palpitations
        - Chest pain
        - Seizure, dizzy, tremor
        - Myalgia, arthralgia

Any side effects however minor should be reported to an obstetrician or anaesthetist.

The patient should be advised to telephone the on call obstetric registrar via switch board if they experience any side effects at home.

Reporting suspected adverse reactions is an important for continual monitoring of risk and benefit of the medicinal product. Report any reaction via the Yellow Card Scheme (website www.mhra.gov.uk/yellowcard)

See Appendix 3 for reaction management algorithm and anaphylaxis protocol

7. Roles and responsibilities

Medical staff

- It is the referring doctor's responsibility to ensure that treatment with intravenous iron is appropriate and other causes of anaemia have been excluded using antenatal anaemia pathway (see **Appendix 1**).
- Contraindications and cautions should have been reviewed and documented and the risk-benefit ascertained. IV iron is not licenced for use in pregnant women of < 13 weeks' gestation.
- An appropriate dose based on patients Hb and booking weight and not exceeding maximum single dose of 20mg/kg should be calculated using Dose Calculation Flow Chart (see **Appendix 2**).

- It is the referring doctor's responsibility to ensure the iron infusion is prescribed on EPR in addition to all anaphylaxis medicines as part of Monofer Maternity Prescribing Plan.
- It is the referring doctor's responsibility to ensure that post infusion blood tests are requested and reviewed post infusion.
- It is the referring doctor's responsibility to act appropriately upon follow up blood tests (e.g. identify and organise repeat infusion if necessary, where there is ongoing anaemia).
- A member of the medical team must be contactable for advice or to attend if the patient requires cannulation, becomes unwell or develops a hypersensitivity or anaphylactic reaction during infusion. Emergency point of contact is the anaesthetic registrar. Consultant anaesthetist on the labour ward is also available for advice or assistance.

Midwifery staff

- Most outpatient antenatal IV iron infusions will be administered in the labour ward high dependency area.
- Check for contraindications and cautions and discuss with medical team if any concerns.
- Cannulate patient if trained to do so.
- Ensure infusion is prepared and administered safely and appropriately.
- Inform the patient about risk of skin discoloration and request that they tell nursing staff immediately if the experience any pain at the cannula site.
- Undertake appropriate monitoring of observations before, during (every 15 mins) and after (every 15 mins for 30 mins) infusion and record on MEWS chart.
- Perform continuous fetal heart rate monitoring before the infusion, during the infusion and for 30 minutes after the infusion has completed. Raise any concerns regarding monitoring to obstetric team.
- Document clinical episode on EPR: attendance, observations, patient status, any events, or complications, CTGs, and provide emergency contact details.
- If an adverse reaction occurs, it should be managed according to the reaction management algorithm (see **Appendix** 3) and must be reported via the yellow card system.
- Guidance on how to reduce and manage IV Iron extravasation is as per Trust:

Extravasation guidelines

- https://freenet2.royalfree.nhs.uk/documents/preview/94307/Extravasation-and-Infiltration-Guidelines-in-the-Management-of-Systemic-Anti-Cancer-Therapy-SACT-and-Non-SACT-Agents

Audit/Monitoring

Element to be audited/ monitored	Lead	Tool	Frequency	Reporting arrangements	Acting on recommendations and Lead(s)	Change in practice and lessons to be shared
Elements of the guideline to be monitored are: • Reason for iron infusion. • Compliance with observations before, during and after infusion.	Lead Pharmacist	Audit tool	Annual	Findings presented at labour ward forum.	A lead will be identified to take each change forward where appropriate.	The monitoring of completion of these actions will remain with this group and follow-up of any newly implemented processes

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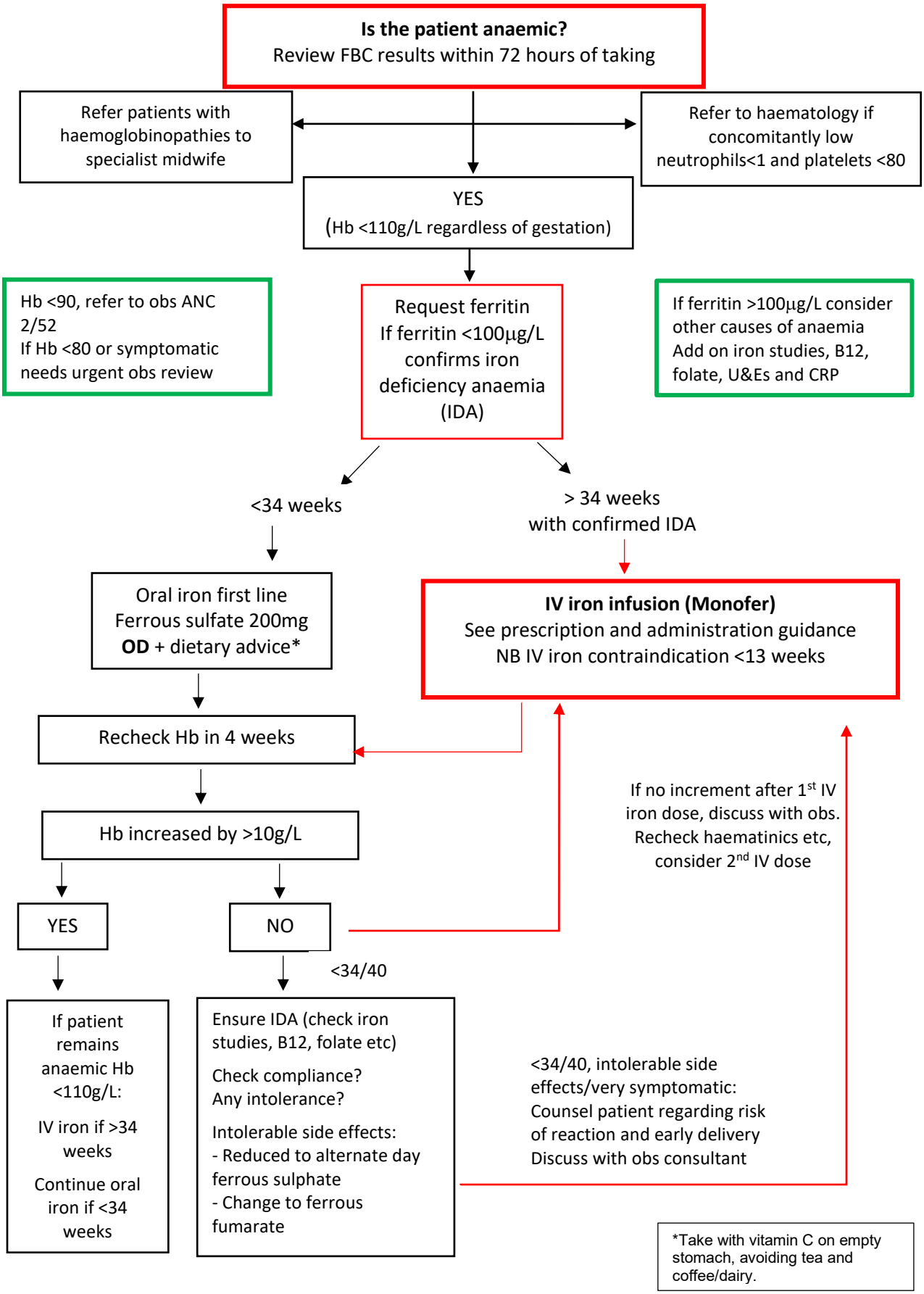
Appendix 1: Antenatal Anaemia Optimisation Pathway: FBC; full blood count, Hb; haemoglobin, IDA; iron deficiency anaemia, Obs ANC; obstetric consultant antenatal clinic, OD; once daily, U&Es; urea and electrolytes



Appendix 2: Dose Calculation Flow Chart

Patient eligible for rapid IV iron infusion with Monofer (according to antenatal anaemia pathway)
Ensure relevant past medical history/allergies assessed and recorded, and contraindications/cautions considered
Obtain patient information: Haemoglobin, height, weight, BMI

Is patient obese (BMI ≥30)?

NO: use actual booking weight

YES: use ideal body weight and maximum single dose calculations

Calculate dose required for full repletion

Hb (g/L)	Patients with booking body weight 50kg to <75kg	Patients with booking body weight ≥ 75kg
≥90	1000mg	1500mg
<90	1500mg	2000mg

Is this dose more than the maximum single dose of 20mg/kg?

NO: the full dose can be given as single infusion

YES: the full dose must be split over 2 infusions
1. The 20mg/kg dose
2. The remainder of the calculated dose 1 week later

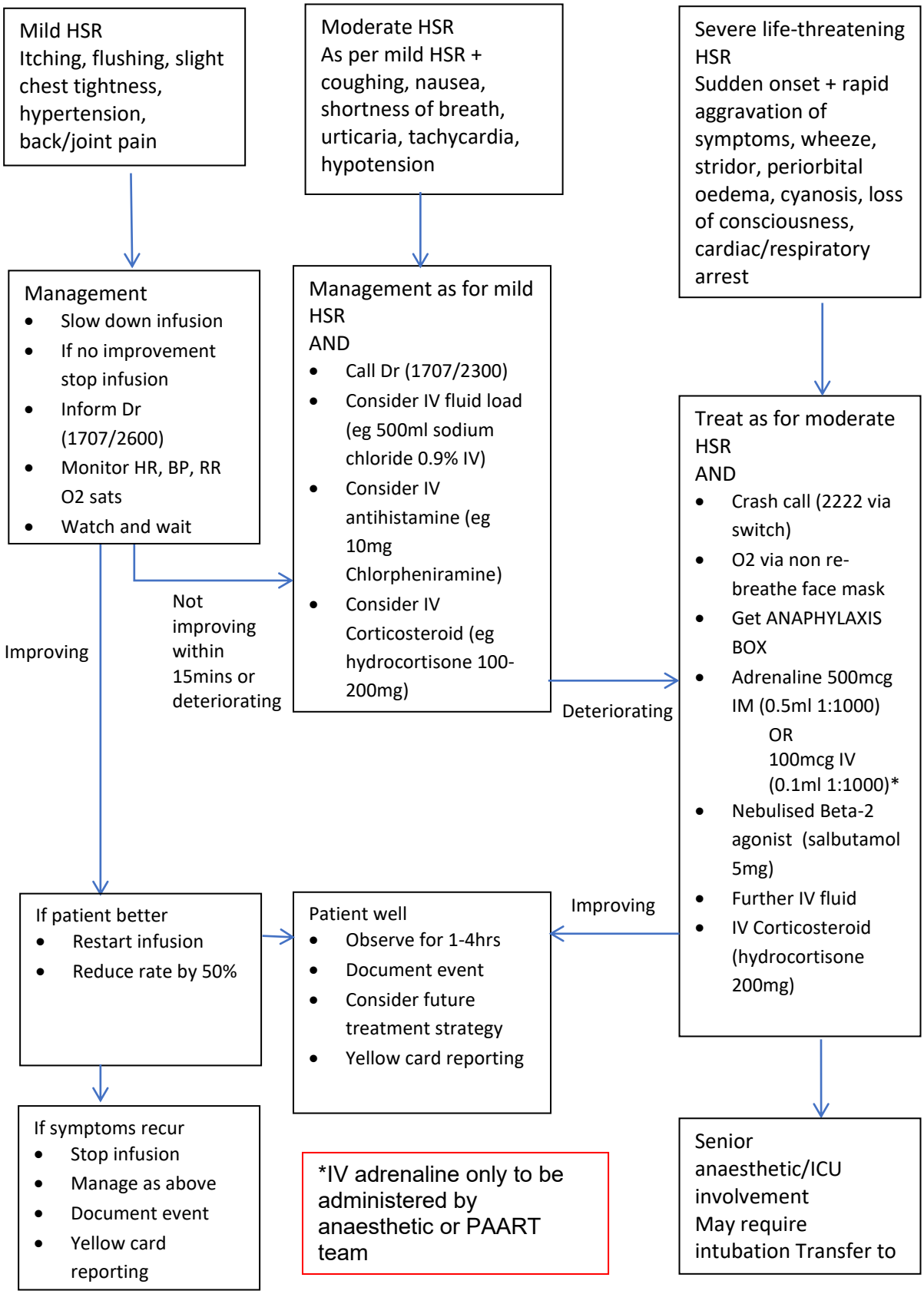
Calculation of ideal body weight if BMI ≥30
Female (kg): [(height (cm) – 154) x 0.9] + 45.5

* Ganzoni formula if weight **<50kg**
Iron dose = Weight Kg x (Target Hb – Actual Hb g/L) x 0.24 + 500mg
Suggested target Hb = 120g/L

Pre-administration questionnaire If any of the below apply the patient will be at greater risk of hypersensitivity reactions				
PMH & Allergies (tick)	**Liver disease**		**Rheumatoid arthritis Or SLE**	
	Asthma		**Previous sensitivity to iron**	
	Eczema		**Other drug allergies**	

Appendix 3: Reaction management algorithm and anaphylaxis protocol: BP; blood pressure, HR; heart rate, HSR; hypersensitivy reaction, O2 sats; oxygen saturation.

Grading and management of acute hypersensitivity reactions (HSR) to intravenous iron infusions



Appendix 4: RFL NHS Foundation Trust Equality and Human Rights Analysis

Name of the policy / function / service development being assessed	**Intravenous iron infusion (Monofer)**	
Division and department	Maternity, W&C	
Details of the person responsible for the EHRA	**Name:** **Job Title:** **Contact Details:**	
What are the main aims and objectives of the policy/ document/ project/ programme?		
Does the document include the equality statement?	**Yes** ☒ **No** ☐ **If no, do not proceed with Equality Analysis until complete**	

5. Engagement and involvement **Who have you consulted with as part of this EA? E.g. Staff Networks, Trades Unions, patients, carers, families, advocacy groups, staff etc.**

6.	a) Impact **Is the policy, project or programme likely to have a differential impact on any of the protected characteristics? If so, is this impact likely to be positive or negative?** **Consider:** How does the policy, project or programme help us meet our public sector duty of: • Eliminating Unlawful discrimination • Advancing Equality of Opportunity • Promoting good relations between groups Does the policy exclude individuals with a protected characteristic e.g. females, older people etc? What does existing evidence show? E.g. consultation from different groups, demographic data, questionnaires, equality monitoring data, analysis of complaints etc. For internal policies, projects, or programmes, you need consider impacts on staff from all protected characteristics. For policies, projects and programmes based on services, you should consider others affected by the proposals such as those accessing the service, taking into consideration the nine protected characteristics and human rights. Please use, the factsheet, the top tips and things to think about when conducting an equality analysis	b) Mitigation **Can any potential negative impact be justified? If not, how will you mitigate, reduce or remove any negative impacts?** Think about reasonable adjustments Consider positive action Consider how you would measure and monitor the impact going forward e.g. equality monitoring data, analysis of complaints.
Equality Group:	**Impact:**	**Mitigation:**
Age	None identified	
Carers / People with caring responsibilities	None identified	
Disability	None identified	
Race / Ethnicity	None identified	
Gender	None identified	

Gender Reassignment	None identified	
Marriage & Civil Partnership	None identified	
Pregnancy & Maternity	None identified	
Religion & Belief	None identified	
Sexual Orientation	None identified	
General Comments across all equality strands		

If the policy, project or programme changes the way that we deliver our services, please complete section 7 - Human Rights duties assessment. You do not need to complete this section if the policy or document is internal-facing, e.g. a People policy – you can skip to section 8 – Action Planning.

8. Action Planning – this should be completed whenever a differential equality impact or human rights impact has been identified			
Action	**Action Owner**	**Timescales**	**Date completed**

9. EA – internal assurance	**If your Analysis relates to staff along with policy, project or programme document should be sent to: Head of Workforce, Staff Experience**
	All other Equality Analysis along with policy, project or programme document should be sent to: Equality and Diversity Manager (Patients and Carers)

10. Sign off and publish	**Governing committee**	See Validation Grid
	Date of approval	See Validation Grid
	Date of publish	See Validation Grid
	Date of review (if relevant)	See Validation Grid

Note that after sign off, EAs will be published on Freenet or internet so should be written with that in mind, for example in relation to person identifiable information.