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MELBOURNE HEALTH

Coroner Jamieson,
Coroners Court of Victoria
65 Kavanagh Street
Southbank VIC 3006

Dear Coroner Jamieson,

Changes implemented following the review of the management and death of Khodr El Mustapha

COR 2013-004295

I write in response to your letter dated 4 December 2015 with attached finding into the death of Mr Khodr El-Mustapha without inquest.

Since Mr El Mustapha's death, two clinical guidelines have been implemented at Melbourne Health to avoid a similar occurrence. The first is the **Iron Infusion Clinical Guideline** (MH02.09.08) , which contains the following information:

- Indications for iron infusion (e.g. inability to tolerate oral iron, gastrointestinal malabsorptive conditions);
- Consent requirements (need for full informed consent including risks and a signing of a consent form);
- Need for appropriate monitoring when an iron infusion is given (including a requirement for a clinical staff member to be present in the first 15 minutes of the infusion, and for a medical doctor to be contactable if not present);
- A reference to the Anaphylaxis Diagnosis and Management guideline as well as the symptoms and signs for early recognition of anaphylaxis. There is now a requirement for a printed copy of this guideline to be available by the patient's bedside when an iron infusion is being performed.

The second guideline is the **Anaphylaxis Diagnosis and Management** guideline (MH02.01.06), which contains the following information:

- Symptoms and signs of anaphylaxis
- Ongoing management of anaphylaxis (with particular reference to the second peak of reaction needing further management as in Mr El Mustapha's case)

Anaphylaxis Diagnosis and Management continues to be a high priority with training during the annual Hospital Medical Officer and Intern Orientation.

Yours sincerely

Dr Karen Ng
Fellow in Medical Management

Enclosure: Iron Infusion Clinical Guideline & Anaphylaxis Diagnosis and Management

PROCEDURE: Anaphylaxis Diagnosis and Management			
Category:	Care Planning and Appropriateness	Ref No.:	MH02.01.06
Sub-Category:	Emergency	Version No.:	1
Issue Date:	20 Feb 2014	Expiry Date:	28 Feb 2017
Department:	Melbourne Health		

DEPARTMENT	Melbourne Health
NAME OF DOCUMENT	Anaphylaxis Diagnosis and Management
NUMBER	MH02.01.06
SPONSOR	Executive Director Clinical Governance and Medical Services
FUNCTIONAL GROUP	Clinical Deterioration Subcommittee, Department of Immunology and Allergy
IMPLEMENTATION STRATEGY	Publish in iPolicy Promote via memo/email update to staff, staff newsletter Include in orientation for all clinical staff Divisional Directors will have a responsibility to ensure this procedure is included in orientation to all clinical staff
EVALUATION STRATEGY	Compliance with this procedure will be evaluated after 12 months, followed by annual audits. (see below) Every in-hospital anaphylaxis should be audited by the parent unit for avoidable factors
EQuIP NATIONAL STANDARD	Standard 9
VERSION SUMMARY	Outlines the procedures for rapid diagnosis and management of anaphylaxis

EXECUTIVE SUMMARY

1. Anaphylaxis is an acute, severe, life- threatening systemic reaction.
2. Intramuscular injection of 500 micrograms of adrenaline is the first line treatment of anaphylaxis in adults. The early use of adrenaline is associated with improved outcomes. Other basic initial treatment includes patient positioning, supplemental oxygen and intravenous fluid resuscitation.

1. ASSOCIATED POLICY

MH02 Care Planning and Appropriateness Policy

2. PURPOSE AND SCOPE

Guideline for the recognition and management of anaphylaxis at Royal Melbourne Hospital (RMH). This procedure applies to all clinical staff within RMH, who are required to work within their scope of practice and over arching policy. Management principles outlined herein are applicable to adults within RMH. Doses are not appropriate for children.

3. DEFINITIONS

Anaphylaxis	A sudden onset, severe, life-threatening generalised or systemic reaction. It is usually, but not always mediated by an immunologic mechanism and results from sudden systemic release of vasoactive mediators from mast cells and basophils.
Angioedema	Swelling in the deeper layer of the skin
Urticaria	Skin rash of acute onset characterised by red itchy lumps

4. RESPONSIBILITIES

4.1. Clinical staff: Ensure that adrenaline injection 1mg/mL (1:1000) is available, has not passed its expiry date and is stored according to manufacturer's instructions, as per MH14.03 Medication Storage and Transport. Ensure that key clinical staff are aware of where adrenaline is stored.

4.2. Clinical staff: Recognise and manage anaphylaxis as per this procedure.

5. PROCEDURE

5.1. Recognition of anaphylaxis

i. Consider a diagnosis of anaphylaxis for:

Any acute illness with typical skin features (i.e. urticarial rash, erythema/flushing or angioedema) PLUS

- Respiratory symptoms
- Cardiovascular; symptoms
- Persistent severe gastrointestinal symptoms.

OR

ii. Any sudden onset of:

- Hypotension
- Bronchospasm
- Upper airway obstruction

NOTE: Even in the absence of typical skin features where anaphylaxis is thought possible; skin signs may be absent in 20% of cases.

5.2. Differential Diagnosis

i. Panic attack;

ii. Idiopathic (non-allergic) urticaria or angioedema;

iii. Sudden onset severe asthma;

iv. Fainting.

5.3. Considerations regarding the mechanism of anaphylaxis (e.g. IgE-mediated or non-IgE mediated) are not relevant for acute management - the treatment is the same.

5.4. Anaphylaxis Treatment for Adult Patients see Appendix 1

5.5. Revert to MH02.01.02 Respond Blue and Medical Emergency Team Response and MH02.01.03 Adult and Paediatric Resuscitation in event of respiratory or cardiac arrest.

5.6. For adrenaline infusion see Appendix 2 and for second line treatments for unresponsive symptoms see Appendix 3.

5.7. Ongoing management

i. Patients should be observed for at least 4 hours after the last dose of adrenaline, in an environment with the facility to provide ECG monitoring, pulse oximetry and non-invasive blood pressure monitoring. Patients should be observed overnight in hospital if they:

i Had a severe or protracted anaphylaxis (e.g. required repeated doses of adrenaline or intravenous (IV) fluid resuscitation);

ii Have a history of asthma or severe/protracted anaphylaxis;

iii Have other concomitant illness (e.g. asthma, history of arrhythmia);

iv Live alone or are remote from medical care; or

v Present for medical care late in the evening.

(Contact Clinical Immunology and Allergy for advice)

ii. Oral non-sedating antihistamines may be used for itch, but have no role in management of respiratory or cardiovascular features.

iii. A 2 day course of corticosteroids (e.g. prednisolone 50mg per day) should be considered to prevent recurrence after a severe reaction, or if there is marked/ persistent wheeze.

iv. Consider prescribing an adrenaline autoinjector with an anaphylaxis management plan (available from www.allergy.org.au) where the allergen is not identified or unavoidable e.g. food, insect sting. Patients prescribed an autoinjector should be trained in its use prior to discharge.

v. All patients experiencing anaphylaxis should have:

i The episode documented in their medical record, as an alert as per MH05.09 Patient Alerts and as an incident in Riskman if appropriate; and

ii an outpatient follow-up within 6 weeks. This is organised with the Clinical Immunology and Allergy Department. Please notify the registrar to expedite.

5.8. Management in high dependency areas

i. Patients requiring IV adrenaline infusions should be transferred to, and monitored within, a high dependency area for the duration of the infusion.

ii. Whilst treatment is usually initiated with intramuscular (IM) adrenaline, the use of dilute IV adrenaline boluses (20 to 100mcg) may be used by experienced staff in areas where cardiorespiratory monitoring is available such as operating theatre and high dependency units.

5.9. Education

i. Anaphylaxis management to be included in the orientation of all clinical staff.

ii. Directors of Medical, Nursing and Allied Health Education will be responsible for ensuring the education processes are in place and reviewed on an annual basis.

5.10. Evaluation and continuous improvement

i. Clinical audit: every in-hospital anaphylaxis should be audited by the parent unit for avoidable factors;

ii. Routine annual compliance monitoring and review of medical records undertaken by the Department of Immunology and Allergy of patients with a primary or associated diagnosis of Anaphylaxis retrieved from Health Information Services.

iii. Review of related incidents reported through RiskMan

6. ASSOCIATED PROCEDURES

6.1. MH01.02 Patient Identification

6.2. MH02.01.02 Respond Blue and Medical Emergency Team Response

6.3. MH02.01.03 Adult and Paediatric Resuscitation

6.4. MH05.09 Patient Alerts

6.5. MH14.01 Medication Prescribing

6.6. MH14.02 Medication Administration

6.7. MH14.03 Medication Storage and Transport

6.8. MH14.08 Adverse Drug Reaction Documentation, Reporting and Processing

6.9. MH19.02 Incident Reporting

7. REFERENCES

7.1. Anaphylaxis - Health Professional Information Paper. Australasian Society of Clinical Immunology & Allergy (ASCIA) September 2013. www.allergy.org.au

7.2. Emergency treatment of anaphylactic reactions - Guidelines for healthcare providers. Resuscitation Council (UK) 2008 as annotated July 2012. www.resus.org.uk

7.3. Simons, F et al. "2012 Update: World Allergy Organization Guidelines for the Assessment and Management of Anaphylaxis." Current opinion in allergy and clinical immunology 12, no. 4 (2012): 389-399.

7.4. Brown, S G A, K E Blackman, V Stenlake, and R J Heddle. "Insect Sting Anaphylaxis; Prospective Evaluation of Treatment with Intravenous Adrenaline and Volume Resuscitation." Emergency medicine journal 21, no. 2 (2004): 149-154.

8. FURTHER INFORMATION

8.1. Clinical Immunology and Allergy

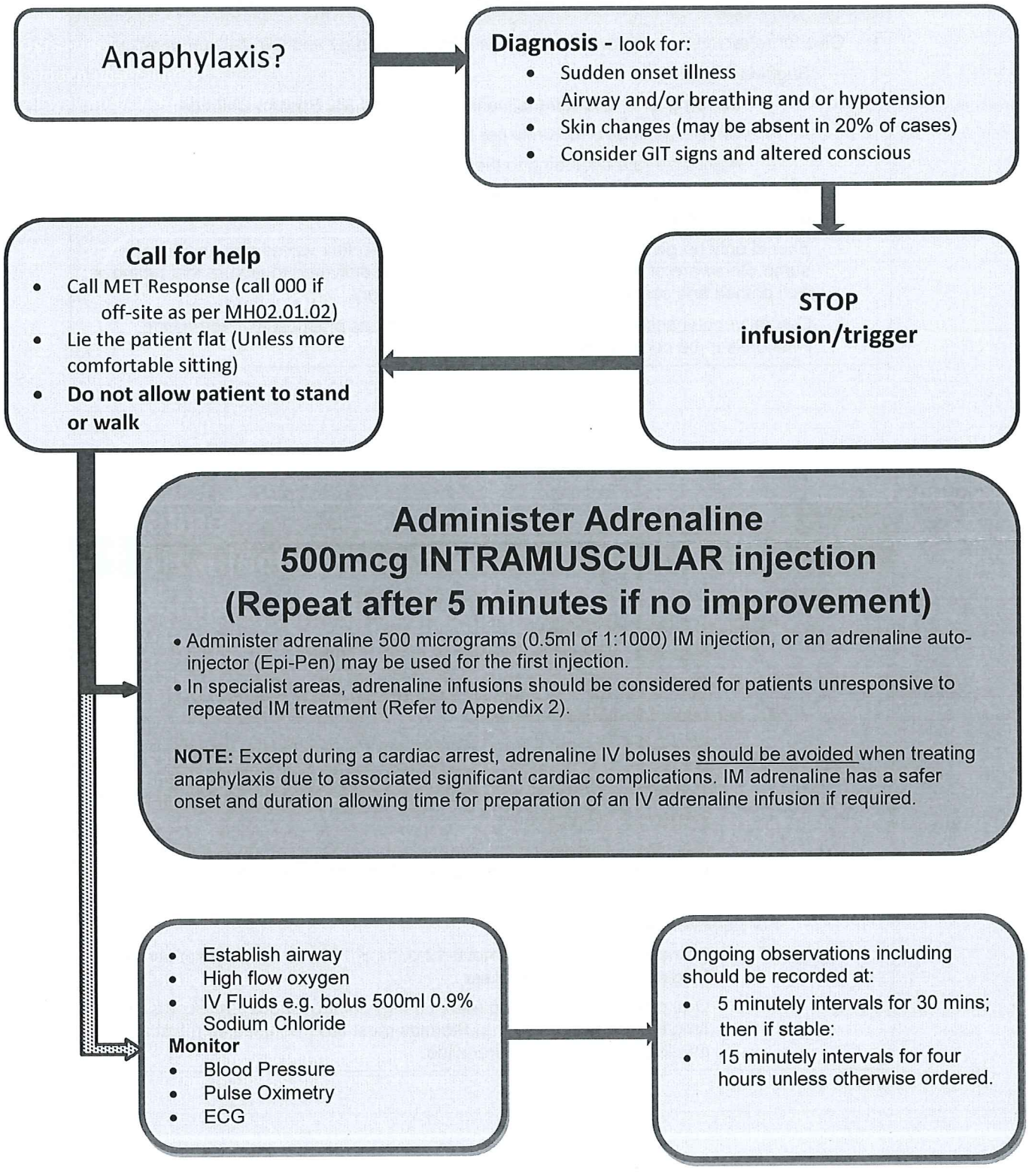
8.2. www.allergy.org.au

9. DOCUMENTATION

10. REVISION AND APPROVAL HISTORY

Date	Version	Author and approval
February 2014	1	Clinical Deterioration Subcommittee, Jo Douglass, Head Department of Immunology and Allergy: Steve Pincus, Emergency; Daryl Williams, Head of Anaesthetics; Nerina Harley, Intensive Care Unit. Approved and authorised by the Clinical Policy Committee.

Appendix 1 Anaphylaxis Treatment for Adult Patients (download printable version)



Adapted from Resus.org.uk: Emergency Treatment of Anaphylaxis 2012

Appendix 2

IV adrenaline infusion for anaphylaxis

- Give for refractory anaphylaxis in liaison with ED/ICU/Allergy and Clinical Immunology.
  - Suggested protocol:
    - Mix 6mg of 1:1000 adrenaline in 100 mL of 0.9% Sodium Chloride
    - Start infusion at 5 to 10mls per hour (0.1microg/kg/min)
    - Adjust the rate according to the clinical response
  - Monitor continuously – ECG and pulse oximetry and frequent non-invasive blood pressure measurements as a minimum.
  - Should only be given with a dedicated line with anti-reflux valves and an infusion pump. Be aware of the small volumes of fluid being delivered to ensure that tubing is well primed and connection is close to patient delivery.
  - Central venous access should be obtained as soon as practicable if adrenaline infusion is to be continuous.

Appendix 3

Second line treatments for unresponsive symptoms

- If adrenaline infusion is ineffective or unavailable, consider:
  - For upper airway obstruction:
    - Nebulised adrenaline (5mg i.e. 5 mL of 1:1000)
    - Consider intubation if skills and equipment are available
  - For persistent hypotension/ shock:
    - Give 0.9% Sodium Chloride (maximum 50 mL/kg in the first 30 min)
    - In patients with cardiogenic shock (especially if taking B blockers) consider an IV/IM glucagon bolus of 1-2 mg. This may be followed by an infusion of 1-2 mg/ hour.
    - Selective vasoconstrictors metaraminol (2-10mg) or vasopressin (10-40 units) after advice from emergency physician, anaesthetist or ICU specialist.
  - For persistent wheeze:
    - Bronchodilators: Salbutamol 8-12 puffs of 100microg using spacer or 5mg salbutamol by nebuliser
    - Oral prednisolone 1mg/kg (max 50 mg) or intravenous hydrocortisone 5mg/kg (maximum 250 mg).Steroids must NOT be used as a first line medication in place of Adrenaline.

INTERNAL GUIDELINE: Iron Infusion Clinical Guideline			
Category:	Care Planning and Appropriateness	Ref No.:	MH02.09.08
Sub-Category:	Care Planning and Appropriateness	Version No.:	1
Issue Date:	24 Sep 2015	Expiry Date:	30 Sep 2018
Department:	Melbourne Health		

DEPARTMENT	Melbourne Health
NAME OF DOCUMENT	Iron Infusion Clinical Guideline
NUMBER	MH02.09.08
SPONSOR	Executive Director, Clinical Governance and Medical Services
FUNCTIONAL GROUP	Iron infusion guideline working group – representatives from Haematology, Gastroenterology, Nephrology, ED, Allergy and Immunology, Pharmacy and Medical Governance.
IMPLEMENTATION STRATEGY	The guideline would be in iPolicy and email notification will be sent to all clinical staff.
EVALUATION STRATEGY	Audit of use of iron infusions
EQuIP NATIONAL CRITERIA	Standard 4 Medication Management
VERSION SUMMARY	New guideline

EXECUTIVE SUMMARY

1. Ensure correct indication for intravenous Iron infusion prescription (as covered in this procedure)
2. Written consent is required (to be documented on a consent form) prior to administration of iron infusions.
3. The presence of a staff member is required by the bedside for the first 15 minutes of iron infusion administration due to the prevalence of allergic reactions. A medical staff member should ideally be on the ward during this time.
4. Ensure 1 ml of 1:1000 adrenaline, 100mg hydrocortisone and a copy of the MH02.01.06 Anaphylaxis Diagnosis and Management available by the bedside. Two syringes of 0.5ml 1:1000 adrenaline will be needed in the event of an anaphylactic reaction.

1. ASSOCIATED MELBOURNE HEALTH POLICY

MH02 Care Planning and Appropriateness Policy

2. PURPOSE AND SCOPE

To provide guidance in the prescription and administration of iron infusions in the context of iron deficiency anaemia.

3. DEFINITIONS

4. RESPONSIBILITIES

4.1. All clinical staff. Medical staff should prescribe the iron infusion on an IV therapy chart. Nursing staff should administer the infusion as per prescription.

5. PROCEDURE

5.1. Approved indications

a Treatment of iron deficiency anaemia where oral treatment has failed or is not appropriate. This includes but is not limited to:

i. Patients with gastrointestinal adverse effects preventing oral treatment (intolerable nausea, abdominal cramps, diarrhea, constipation, or vomiting).

ii. Patients suffering from malabsorptive conditions such as Crohn's disease and nonspecific colitis

iii. Patients with pathologic conditions of the upper gastrointestinal tract (peptic disease, gastritis, diaphragmatic hernia) that cause chronic prolonged bleeding and consequently iron deficiency anaemia.

iv. Patients with chronic kidney disease, where absorption of oral or dietary iron intake is compromised, or to increase the effectiveness of recombinant Erythropoietin for patients with renal anaemia and low serum iron

5.2. Informed written consent MUST be taken (to be documented on the consent form) prior to commencement of an iron infusion. An iron infusion brochure must be provided to the patient.

5.3. Iron polymaltose is preferred as the first line iron preparation.

5.4. As an alternative to iron polymaltose, ferric carboxymaltose can be administered, particularly in situations where there are time constraints in terms of duration of infusion (e.g. infusion administered in an Outpatient setting).

5.5. How to select the appropriate formulation for your patient

Patient	Iron polymaltose	Ferric carboxymaltose
Inpatient – no history of allergy to iron infusion	✓	×
Inpatient – history of allergy to iron infusion	×	✓
Outpatient – no history of allergy to iron infusion	×	✓
Outpatient – history of allergy to iron infusion	×	×

Note- Patients with multiple allergies to iron preparations please consider referral to Allergy and Immunology.

5.6. A staff member is required by the bedside for the first 15 minutes of iron infusion.

5.7. It is preferable that iron infusions are administered in the day procedure units.

5.8. Emergency resuscitation equipment, e.g. oxygen/suction, must be on hand when patients are receiving a test dose of iron.

5.9. As a precaution, Adrenaline 1:1000 and Hydrocortisone 100mg must be available at all times during administration of intravenous iron.

5.10. All drugs and intravenous solutions must be checked as per MH14.02 Medication Administration.

5.11. Do not add any other medications to the iron infusion or mix in the same line.

5.12. Equipment

a Iron preparation

b Intravenous giving set

c Infusion pump

d Disposable gloves

5.13. Intravenous iron polymaltose administration

a Refer to MH14.50.07 Iron Polymaltose

5.14. Intravenous iron sucrose (for hemodialysis patients only) administration procedure

a Please refer to product information for iron sucrose

5.15. Intravenous ferric carboxymaltose administration

a Refer to MH14.50.08 Ferric Carboxymaltose

5.16. Adverse reactions

a Anaphylaxis

i. Recognition of anaphylaxis

- An acute illness with typical skin features (i.e. urticarial rash, erythema/flushing or angioedema)
- Respiratory symptoms, and/or
- Cardiovascular symptoms, and/or
- Persistent, severe gastrointestinal symptoms

- OR, any sudden onset of:
  - Hypotension, and/or
  - Bronchospasm, and/or
  - Upper airway obstruction
- Where anaphylaxis is considered possible even if typical skin features are not present

ii. Action:

- Cease infusion and refer to MH02.06.01 Anaphylaxis Diagnosis and Management. Please note monitoring post anaphylaxis guidelines within document.

b Other hypersensitivity reactions

i. Symptoms include skin features (i.e. urticarial rash erythema/flushing or angioedema) WITHOUT the potentially life threatening features above.

ii. Action:

- Cease infusion
- Treat patient symptomatically e.g. hydrocortisone or antihistamine, as per treating team
- Frequent observations (every 10 minutes) for next hour due to high level of suspicion for anaphylaxis.

c Post-transfusion reactions

i. Symptoms include nausea, headache, fever (usually hours/days post infusion); arthralgia/myalgia

ii. One to two days post infusion: headache, mild fever, joint and muscle aches

iii. Action:

- Treat patient symptomatically as per home team

6. ASSOCIATED POLICIES/PROCEDURES

6.1 MH02.02.01 Consent

6.2 MH14.02 Medication Administration

6.3 MH02.01.06 Anaphylaxis Diagnosis and Management

6.4 KCS04.01.04 Management of Renal Anaemia (Includes Iron Replacement)

6.5 KCS01.02.11 Intravenous Iron Administration During Haemodialysis

6.6 MH14.50.07 Iron Polymaltose

6.7 MH14.50.08 Ferric Carboxymaltose

7. REFERENCES

7.1. Iron Polymaltose Product Information

7.2. Iron Carboxymaltose Product Information

8. FURTHER INFORMATION

8.1. Pharmacy

9. DOCUMENTATION

9.1. Generic consent form

9.2. IV infusion chart

9.3. Anaphylaxis Diagnosis and Management

10. REVISION AND APPROVAL HISTORY

Date	Version	Author and approval
Draft	1	Dr Giles Kelsey (Haematology), Dr Kymble Spriggs (Allergy and Immunology); A/Prof Nigel Toussaint (Renal); Prof Geoff Hebbard (Gastroenterology); Dr George Braitberg (ED); Dr Karen Ng, Medical Management Fellow; Dr Dayu Gai, HMO Improvement Officer; Dr Elizabeth Judson, Medical Legal HMO