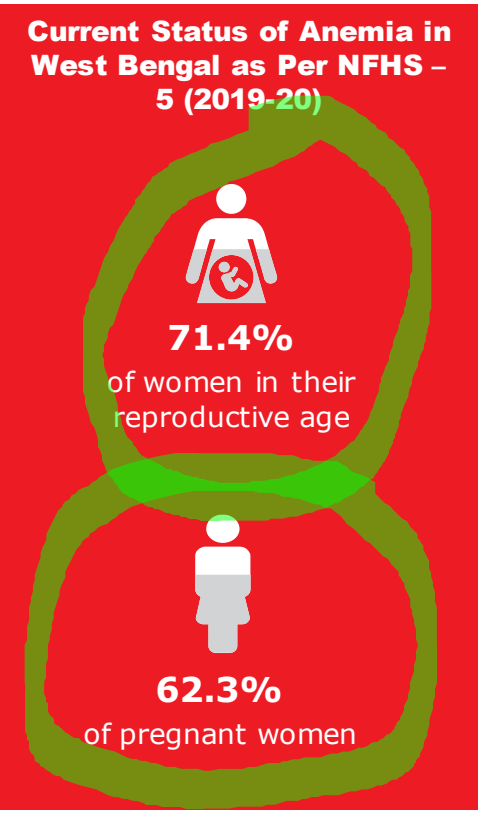
Use of Intravenous Iron Among Pregnant Women (PW)

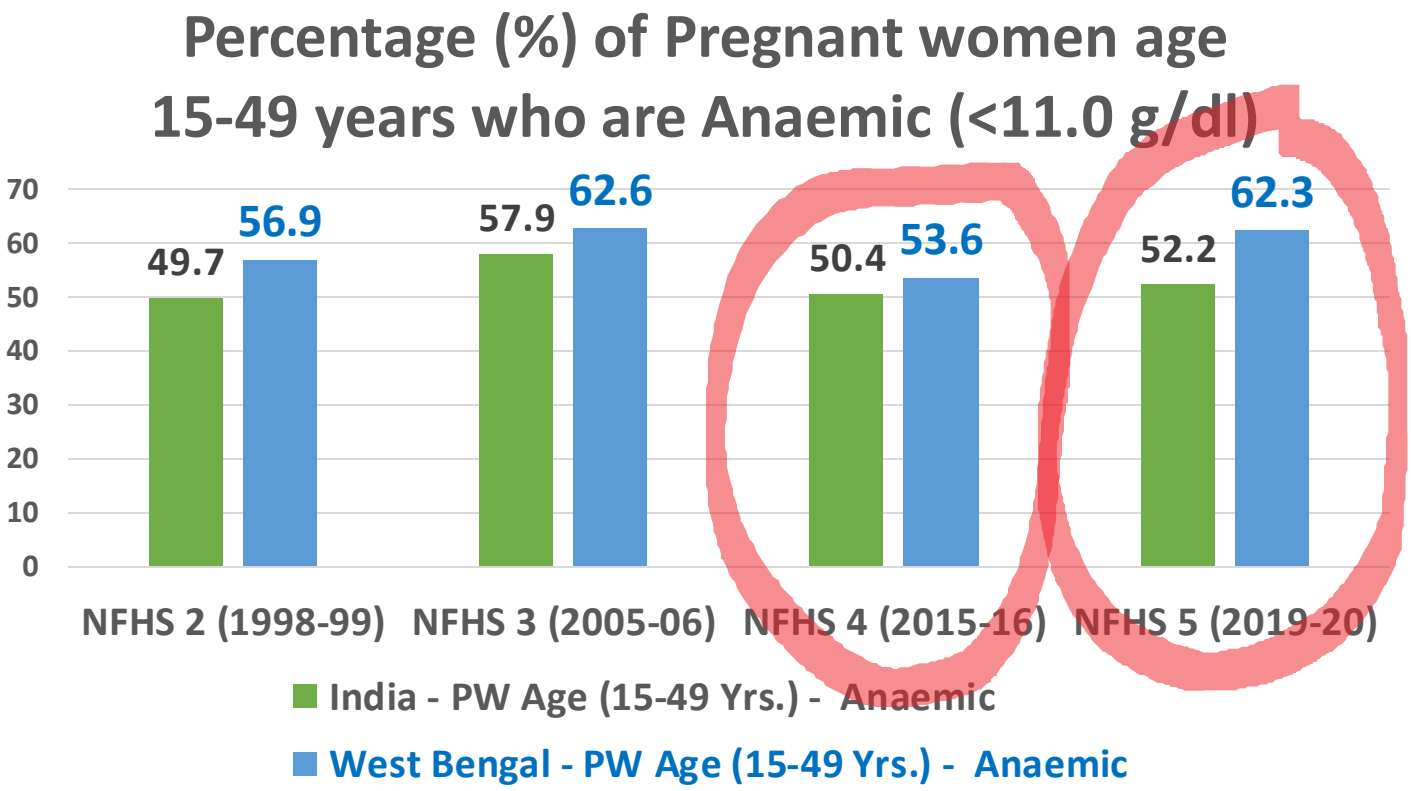
- Guidance Note Explanation

February, 2024

Maternal Health Division
Health & Family Welfare Department
Government of West Bengal

A Snapshot of Anemia in Pregnant Women India and West Bengal





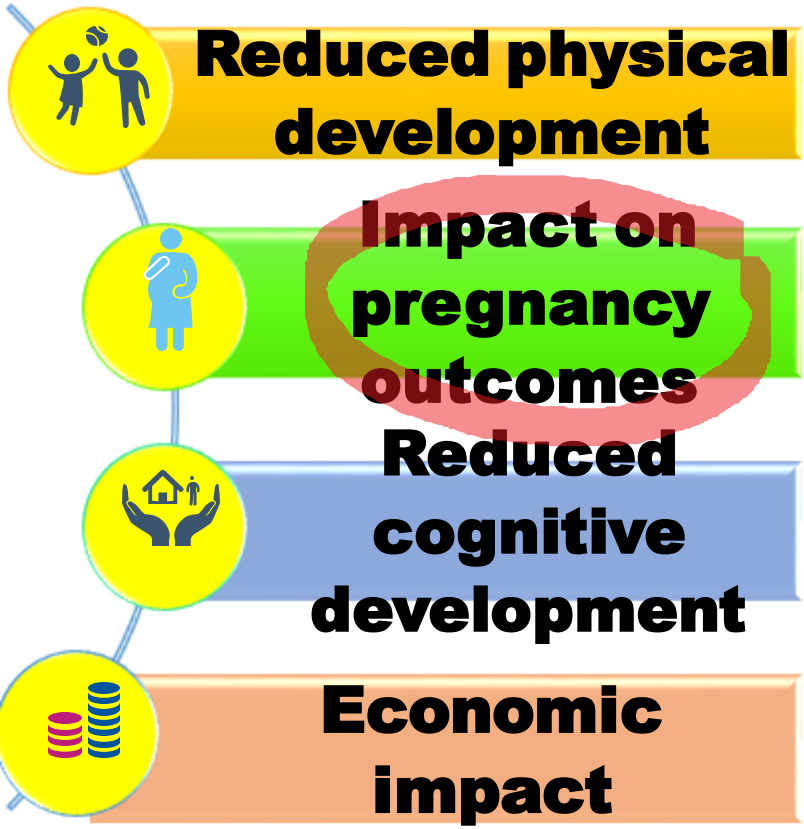
Anemia Status as per Haemoglobin Level (g/dl)

Anemia status	Haemoglobin level (g/dl)
No Anemia	≥ 11.0
Mild Anemia	10.0 - 10.9
Moderate Anemia	7.0 - 9.9
Severe Anemia	<7 (5-6.9)
Very Severe	<5

Causes of High Burden of Anemia

Low Iron Stores	Dietary	Iron Loss	Maternal Anemia
• Poor iron stores from infancy, childhood deficiencies and adolescent Anemia	• Excessive consumption of 'Iron Inhibitors' (tea, coffee, calcium-rich foods) and low intake of 'Iron Enhancers' (Vitamin C etc.) • Low bioavailability of dietary iron • 50% of the population is consuming < 50% RDA • GI problems: malabsorption	• Due to parasitic load (malaria, intestinal worms)	• Increased iron requirement • Teenage pregnancy • Repeated pregnancies with less than 2 years interval • Blood loss : Abortion, APH and PPH.

Public Health Implications of Anemia



- Decreased work output and work capacity
- Physical and cognitive losses due to IDA in South Asia are staggering: close to **$ 4.2 billion annually** in Bangladesh, India and Pakistan

- **About 20 % of maternal deaths are caused by Anemia worldwide**
- **Preeclampsia,PPH, sepsis**
- **low birth weight and still births, preterm birth**

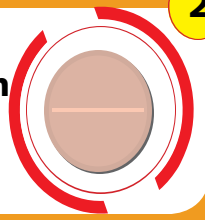
- In the WHO/World Bank rankings, Iron Deficiency Anemia is the **third leading cause of DALYs lost** for females aged 15–44 years and **1.18 % of Gross Domestic Product (GDP) loss**. Median total loss (physical and cognitive) combined are 4.05% of GDP in developing countries.

Six Ongoing Interventions to address burden of Anemia

1. 

Prophylactic iron folic acid supplementation

2. **Periodic deworming of children adolescents, pregnant women**



3. 

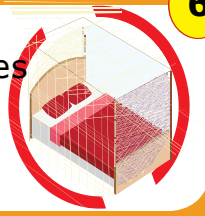
Intensified year-round Behavior Change Communication Campaign *Solid Body Smart Mind* ,delayed cord clamping

4. **Testing of anemia using digital methods and point of care treatment**

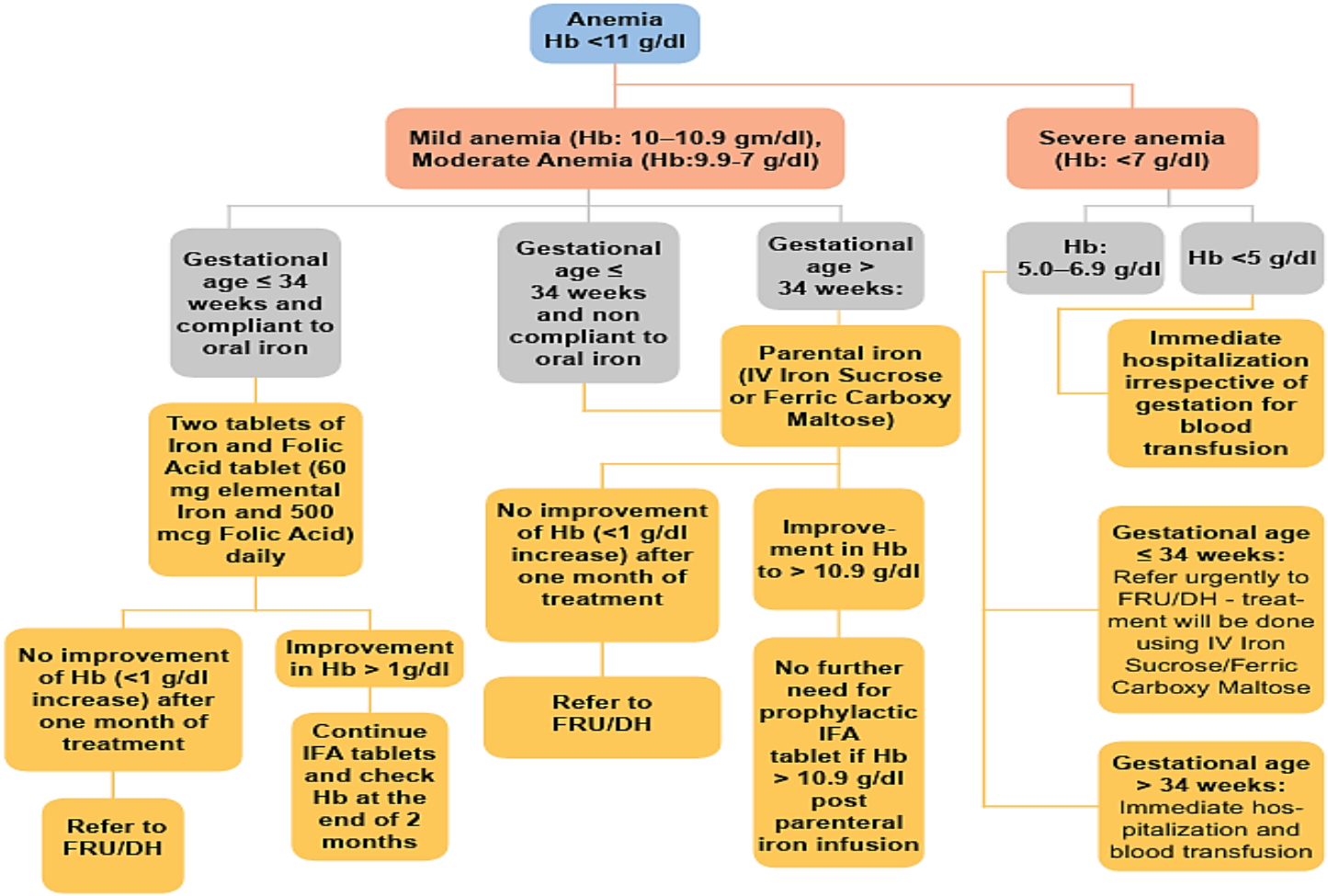
5. 

Mandatory provision of iron and folic acid fortified foods in **public health programmes**

6. Addressing non-nutritional causes of anemia in endemic pockets, with special focus on malaria, haemoglobinopathies and fluorosis



Treatment of Anemia Amongst Pregnant Women



Flow Chat Source: Anemia Mukt Bharat Training Tool Kit

Anemia Management Protocol for Pregnant Women: Mild to moderate

ORAL IRON is Gold standard

First line treatment option for mild, moderate anaemia in pregnancy<34wks

Two tablets of iron and folic acid tablet (60 mg elemental iron and 500 mcg folic acid) daily, orally given by the health provider during the ANC contact.

Follow up : expected rise 1gm%or more in 4wks.

Refer : to FRU if hb rise is less than 1gm%

Disadvantages of Oral Iron

- **GI side effects**
- **Non compliance**
- **Poor absorbtion** : faulty intake, malabsorption and Diarrhoea.

ADVANTAGES OF Parenteral IRON

- **Parenteral iron circumvents the natural gastrointestinal regulatory mechanisms to deliver non-protein bound iron to the red blood cells. Ensures Iron administration.**

- **Malabsorption, intolerance and non compliance can be overcome.**

- **replenish iron stores**
- **Rapid rise / enhanced rise of HB??**

Indications of Parenteral iron

1. **First line :**

- **Moderate Iron deficiency anaemia, (7-9.9gm%), >=34wk**
- **Severe IDA, hb 5-6.9gm% at 13-34wks**

2.Second line : Moderate IDA <34 wks, noncompliant / intolerant/ not responding to oral iron.

Contraindications of Parenteral Iron

- **Known hypersensitivity**
- **First trimester of pregnancy.**
- **Iron overload serum ferritin >150 ng/mL**
- **Thalassaemia, Sickle cell anaemia, Haemolytic anaemia.**
- **Chronic liver disease, Chronic kidney disease, Cardiac failure.**

PREREQUISITE FOR PARENTERAL IRON

- Investigations :**Serum Ferritin is gold standard.** HB %, CBC(MCV, MCH, MCHC) and RDW, HPLC.
- Availability for **monitoring and resuscitation fa**cility in view of any adverse reaction.
- Oral iron to be stopped 24hours prior to infusion.

Intravenous (IV) iron for Pregnant Women

Types of Intravenous Iron Preparations	
Iron sucrose (IS)	**Ferric Carboxymaltose (FCM)**
Iron sucrose is an intravenous iron formulation with a high molecular weight iron (III) – hydroxide with sucrose.	FCM (Ferric Carboxymaltose), a macromolecular ferric hydroxide carbohydrate complex with a ferric hydroxide core stabilized by a carbohydrate shell.

Dosage calculation

Iron Requirement for Intravenous Iron Administration can be Calculated using **Ganzoni's Formula**

Total Iron Deficit (mg)= 2.4 X Body weight[a] (kg) X (target Hb in g/dl[b] - actual Hb in g/dl) + 5

Pre-pregnancy weight

If pre-pregnancy weight is not available, weight recorded during the first visit of first trimester to be used.

Target Hb for pregnant women = 11.0 gm/dl.

The allowance for reserve iron is mg in pregnant women weighi 35 kg (If the pregnant wom weight is <35 kg, allowance for store is 15 mg/kg body weight

- **Example**
- **If a pregnant woman has body weight of 50kg and HB is 7gm%**
- **2.4x50x(11-7) +500=980mg**

Preparation	Mg/mL	Maximum single dose	Maximum Frequency/wk	Rate of infusiin	Maximum Tital ddise
Iron Sucrose	20mg(5ml vial)	**200mg**	3times a wk(600mg)	**200mg in 100ml of NS. 20-30drops/min for 1^{sst} 5minutes, then 80-90drops/min in next 20-25 min.**	**1000mg**
Iron ferric Carboxymaltise(FCM)	50mg/ml, (10ml/20ml vial)	1000mg	Once a week, repeat after 7/14days	100ml of NS, over 15minutes.	1500mg

Iron Sucrose (IS) Administration

1. Iron sucrose is available in a 5 ml vial, containing 20 mg of elemental iron per ml of iron sucrose.

2. Intravenous iron sucrose should be administered as a slow infusion of 200 mg/dose in 100 ml of 0.9% saline, delivered over 20-30 minutes.

3. During the initial five minutes, the infusion should be administered at a rate of 20-30 drops/minute, gradually increasing to 80-90 drops/minute. Subsequent doses can be given over a period of 20 to 25 minutes.

4. It is crucial to administer the drug at this specified rate, as both too slow or too fast rates have been associated with side effects.

5. The maximum dose of iron sucrose should not exceed 600 mg (3 doses of 200 mg each) in a week.

Iron sucrose administration

7. Iron sucrose administration should take place at PHC or higher level under the supervision of a medical officer.

8.Vital signs, including blood pressure, heart rate, respiratory rate, temperature, and fetal heart rate, should be monitored before, during, and at the end of the infusion.

9.To prevent permanent skin discoloration due to extravasation of IVIS, the i.v. cannula's patency must be checked by flushing normal saline before starting.

10.Pregnant women should be observed for 30 minutes post infusion for any adverse events.

10. test dose is not required for IS.

Iron Sucrose (IS) Administration – Key Points

1. Do not administer more than 600 mg of iron per week (as iron sucrose). However the total dose should not exceed 1000mg (5vials) in one pregnancy.
2. Do not administer by subcutaneous or intramuscular route.
3. Sodium chloride 0.9% is the only diluent to be used.
4. IV IS does not require admission, can be a day procedure.

Ferric Carboxy Maltose (FCM) administration

1. FCM is available in 10 ml and 20 ml vials. Each 10 ml vial contains 500 mg of FCM equivalent to elemental iron. Similarly, each 20 ml vial contains 1000 mg of FCM equivalent to elemental iron.

2. FCM will be administered as an intravenous infusion based on the calculated dose requirement with 100 ml of 0.9% Normal Saline Solution over 15 minutes

3. The maximum dose per session will be 1000 mg
4. If subsequent doses are needed, 7th and 14th days can be planned for administration

FCM administration

5.FCM should be administered at PHC or higher level under the supervision of the medical officer.

6.Vital signs such as blood pressure, heart rate, respiratory rate, temperature, and fetal heart rate should be monitored before, during, and at the end of the infusion

7. avoid permanent discoloration of the skin due to extravasation of FCM, the patency of the cannula must be checked by flushing normal saline before the initiation of treatment.

8. Pregnant women should be observed for 30 minutes post infusion for any adverse events.

9. A test dose is not required for FCM.

FCM Administration – Key Points

1. Do not administer more than 1000 mg of FCM per week.
2. Do not cross 1500 mg total dose in one pregnancy.
3. IV FCM does not require admission , can be a day procedure.
4. Do not give by subcutaneous or intramuscular route.
5. Sodium chloride 0.9% is the only diluent to be used.

Expected rise of HB%

- **The expected increase in hemoglobin level for pregnant women with severe and moderate anemia is approximately 2.5 gm/dL and 1.6 gm/dL, respectively after 3 weeks of complete dose of IV iron sucrose treatment.**

- ***National expert Committee**

Advantages Of Ferric Carboxymaltose (FCM) Over Iron Sucrose By National Expert Committee:

Faster Haemoglobin rise	• FCM brings about greater and faster haemoglobin increase in treatment of anaemia as compared to iron sucrose.
Higher Stability	• FCM exhibits higher stability than iron sucrose.
Lower Antigenicity	• Antigenicity is much lower with FCM in comparison to iron sucrose
Shorter Administration Time	• FCM usually requires a shorter administration time, approximately 15 minutes , compared to iron sucrose, which may take around 30 minutes
Efficient Dose Delivery	• Maximum dose and total replacement dose in a single infusion is higher for FCM, allowing for the efficient delivery of a substantial amount of iron in one administration.

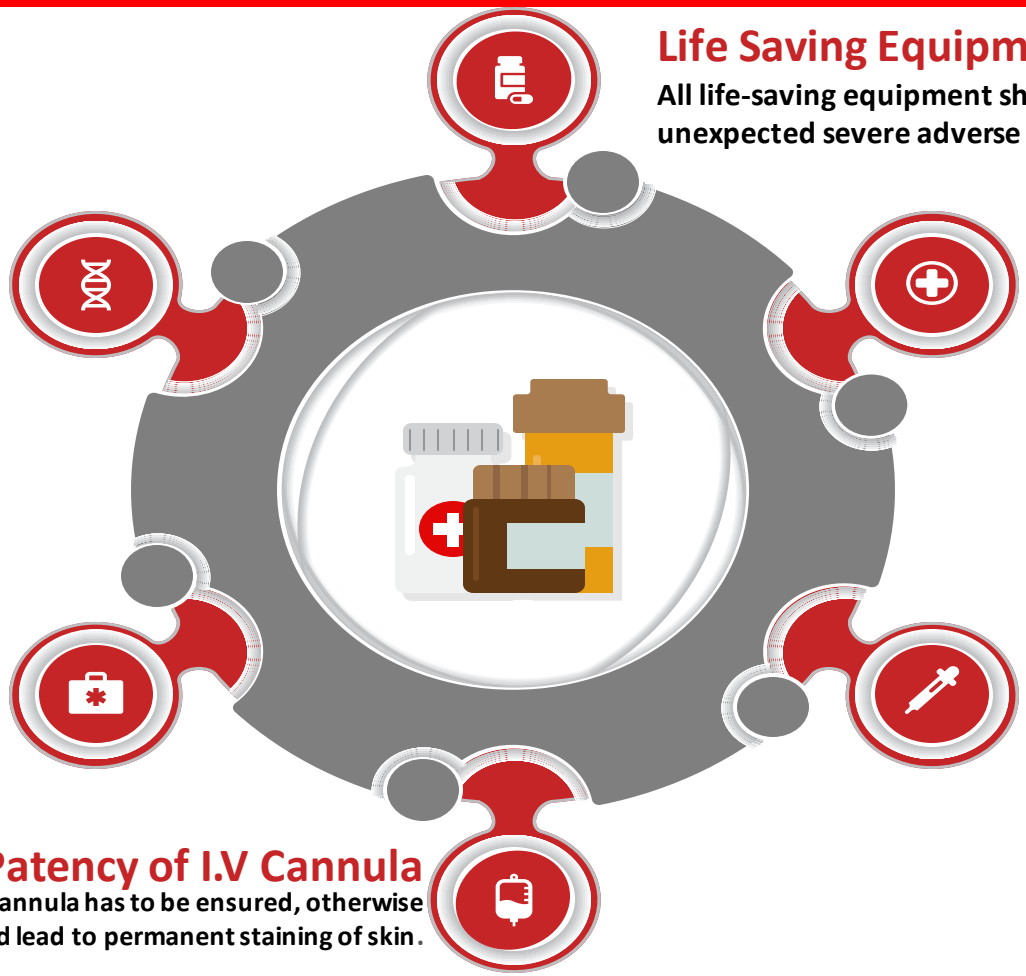
Precautions During Intravenous Iron Administration

Reaction

In case of any reaction, stop the intravenous iron administration and give one ampoule of inj. Avil (Pheniramine), one vial of inj. Hydrocortisone intravenously immediately and contact the medical officer on duty.

Life Saving Equipment

All life-saving equipment should be available to deal any unexpected severe adverse reaction.



Hand Hygiene

Hand hygiene shall be performed before and after the contact with pregnant women

Do not Store

Discard the remaining unused drug in the vial after withdrawing the required dose. Do not store the remaining Iron sucrose or FCM for later use

Sterile Sets

Use sterile and disposable intravenous infusion set, i.v. cannula and syringe.

Patency of I.V Cannula

Patency of i.v. cannula has to be ensured, otherwise extravasation of iron could lead to permanent staining of skin.

References

1. Guidance Note on the use of Intravenous iron among pregnant women (Nutrition Division, Ministry of Health and Family Welfare, Government of India).

2. Anemia Mukt Bharat Training Tool Kit.

3. National Family Health Survery (NFHS) Report.