REVIEW ARTICLE

# Federation of Obstetric and Gynecological Societies of India Consensus Recommendations for the Management of Postpartum Anemia with Specific Reference to Usage of Ferric Carboxymaltose

Shantha Kumari Sekaran[1], Basab Mukherjee[2], Jai Bhagwan Sharma[3], Girija Wagh[4], Kavita Bapat[5], Reena Wani[6], Sneha Bhuyar[7], Vaishali Chavan[8], Aruna Suman[9], Chaitanya Ganpule[10], Deepa Mukundan[11]

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## Abstract

**Background:** India has a substantially high burden of postpartum anemia (PPA). Several countries have guidelines regarding screening, diagnosis, and management of PPA. However, different modalities of treatment are followed in clinical practice, and consensus on management of PPA is lacking among the Indian practitioners.

**Aim:** To review the current evidence and come to a consensus regarding definition, classification, appropriate time of screening and diagnosis, along with management of PPA, with specific reference to usage of ferric carboxymaltose (FCM).

**Methodology:** The core committee comprised of 11 obstetricians. Using the modified Delphi method, eight statements were created, discussed, and ranked by the obstetricians and recommendations were recorded. Statements were ranked on a 9-point Likert's scale ranging from 1 (strongly disagree) to 9 (strongly agree). For each statement, the scores of all the obstetricians were summed and an average score of ≥7.00 was required to attain the consensus.

**Results:** The cut-off hemoglobin (Hb) levels of above 11 gm/dL within 1-week postdelivery is termed as PPA. Postpartum anemia severity can be graded as mild, moderate, and severe with Hb levels of 10–10.9, 7–9.9, and below 7 gm/dL, respectively. All postpartum women (PPW) should be universally screened with Hb estimation and complete blood count (CBC) within 24–48 hours of delivery, prior to discharge, and repeat Hb estimation should be performed at 6 weeks postdelivery. Ferric carboxymaltose is superior to oral and other intravenous (IV) iron therapies and all PPW should be discharged with a single dose of FCM after an informed decision. Additionally, oral iron (OI) is not required during or following FCM administration, the decision to start oral therapy can be taken after 4 weeks of discharge, if required.

**Conclusion:** Ferric carboxymaltose is a safe, effective, well-tolerated, and economical option for managing PPA and shall be practiced in all women with PPA before discharge.

**Keywords:** Ferric carboxymaltose, Iron deficiency anemia, Postpartum anemia, Postpartum care.

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## Introduction

Postpartum period (PPP), ranging from childbirth to 6 weeks, is the most crucial time for the survival and well-being of the newborn and the mother. During this period, postpartum anemia (PPA) is a frequently observed complication, and a critical factor for maternal morbidity and mortality.[1,2] It has a high prevalence in developing countries (50–80%) and is a major public health issue.[1] In India, the prevalence of anemia is very high. Anemia is reported in around 60% pregnant women, and it is the reason for maternal deaths in 20–40% of patients. Around three-quarters of the maternal deaths attributed to anemia in South Asia are observed in India.[3] Additionally, the prevalence of PPA is around 65%, ranging from 26.5 to 94.6% in rural parts of Karnataka and Rajasthan.[3–5] Another study reported that the prevalence of PPA in urban Puducherry was 76.2%.[6] A recent study demonstrated that anemia was more prevalent among postpartum women (PPW) (63%) than pregnant (59%) and nonpregnant nonlactating women (53%).[7] Thus, India has a significant burden of PPA.

In developing parts of the world, including India, the principal factor for PPA is iron deficiency anemia (IDA) and/or

[1]Department of Obstetrics and Gynaecology, Yashoda Hospital, Hyderabad, Telangana, India

[2]Department of Obstetrics and Gynaecology, Manipal Hospital, Kolkata, West Bengal, India

[3]Department of Obstetrics and Gynaecology, All India Institute of Medical Sciences, New Delhi, India

[4]Department of Obstetrics and Gynaecology, Bharati Vidyapeeth University Medical College, Pune, Maharashtra, India

[5]Department of Obstetrics and Gynaecology, Bapat Hospital, Indore, Madhya Pradesh, India

[6]Department of Obstetrics and Gynaecology, Dr. R.N. Cooper Hospital & H.B.T. Medical College, Mumbai, Maharashtra, India

[7]Department of Obstetrics and Gynaecology, Sukhkarta Hospital, Yavatmal, Maharashtra, India

[8]Department of Perinatology, The Federation of Obstetric and Gynecological Societies of India

[9]Department of Obstetrics and Gynaecology, Government Medical College, Jagtial, Telangana, India

[10]Department of Obstetrics and Gynecology, Pearl Women's Hospital and Yash-IVF, Pune, Maharashtra, India

prepartum iron deficiency (ID) together with underlying diseases (hemoglobinopathies), infections (malaria and worm infestation), acute bleeding anemia during labor, nutritional deficiency (vitamins A and B12; riboflavin; and folate), and low socioeconomic class.[1,2,8,9] Also, PPWs are at risk of anemia due to poor iron reserves prior to and in pregnancy, blood loss during labor, increased requirement during lactation, and inadequate intake of iron supplements during PPP.[10] Other related factors are low education level, poor socioeconomic status, younger age, higher parity, less birth spacing, lack of antenatal care, poor compliance to oral iron (OI) and folic acid supplements during pregnancy, blood loss, cesarean delivery, and complications during delivery. Postpartum anemia may also be the result of postpartum hemorrhage and prepartum anemia in 5–25% women.[11]

Maternal health during gestation and PPP has a bearing on the breastfeeding potential and the anemia risk during infancy.[1] The other adverse outcomes of PPA include easy fatiguability, lower work performance, palpitations, breathlessness, emotional instability, decline in cognitive abilities as well as higher chances of infections, venous thromboembolism, and postpartum depression.[6,10] Additionally, PPA results in poor interaction between mother and child, and delay in developmental milestones in infants.[12] These changes are more significant among women from deprived sections of society, including the developing part of the world. In low-income women, the recovery from PPA is slower compared to those coming from well-off families.[13,14] Additionally, a high prevalence of IDA is reported in pregnant women from the developing part of the world.[15,16]

Even though PPA possesses a substantial burden, and its adverse effects are reported throughout the world, it has not received sufficient attention even in developed parts of the world.[1,2] Additionally, the presenting symptoms rarely lead to hospital visits and usually are mistaken for lifestyle alteration following the arrival of a newborn. Thus, screening for PPA has previously been proposed to facilitate early treatment initiation.[17,18] However, the absence of global consensus regarding the diagnosis and treatment of PPA is a dilemma that has led to restricted information on PPA.[2,9,11,19]

These findings suggest that certain obstetricians may have queries related to adequate postpartum management.[20,21] The available guidelines suggest selective patient screening, in those with significant blood loss or anemia during pregnancy.[22] However, significant blood loss has not been defined, thereby adding to the ambiguity. Additionally, postdelivery hospitalization provides an excellent opportunity for the diagnosis and treatment of anemia, as the next opportunity for evaluation is only after 4–6 weeks, and 10–40% PPWs do not utilize the available healthcare services.[23] However, to plan adequate treatment measures, the available evidence is critical to inform the Obstetricians regarding the current scenario and guide them to ensure desirable health for PPW and infants. Thus, efforts were directed at reaching a consensus among the expert Obstetricians regarding the definition, classification, screening, diagnosis, and management of PPA in Indian women.

## Methodology

The core committee of subject experts in obstetrics and gynecology for framing consensus recommendations included 11 obstetricians. Recently published consensus statements in Switzerland (2011), and Tukey (2015); clinical practice recommendations in India (2017); and guidelines in the United Kingdom (2020), and the World Health Organization (WHO) were considered as reference standards.[24–28] A comprehensive literature review was focused on the classification, screening, diagnosis, and treatment of PPA with a special focus on ferric carboxymaltose (FCM). The core committee members assessed the drafted statements and gave opportune recommendations to come to an agreement and then the statements were consolidated, as regarded suitable. These consensus statements are based on the current evidence and experience of the obstetricians and extensive review by additional experts where strong evidence was absent. We are of the opinion that this consensus statement will act as a platform for all obstetricians, as part of a renewed focus on a comprehensive management approach to PPA with FCM.

[11]Department of Obstetrics and Gynaecology, Assured Best Care Hospital Pvt Ltd., Tiruchirappalli, Tamil Nadu, India

**Corresponding Author:** Shantha Kumari Sekaran, Department of Obstetrics and Gynaecology, Yashoda Hospital, Hyderabad, Telangana, India, Phone: +91 9848031857, e-mail: drshanthakumari@yahoo.com

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## Reaching the Consensus with Modified Delphi Method

Obstetricians with at least 5 years of experience related to PPA were recognized and sought for discussion. These eligible obstetricians could lead and were willing to make decisions to come to a consensus. The consensus meeting was called by the Working Committee, and 11 Indian obstetricians participated in the process.

The consensus was reached by the modified Delphi method, and the statements were drafted and circulated among the obstetricians. A total of eight statements were used, and each obstetrician was asked to rate them with the help of a 9-point Likert's scale, ranging from 1 (strongly disagree) to 9 (strongly agree). For each statement, the scores of all the obstetricians were summed and the average was calculated.[29]

## Attaining the Consensus

Statements with an average score of ≥7.00, ≥6.50, and <6.50 were regarded to have attained the consensus, near consensus, and no consensus.

*Statement 1*

The cut-off Hb levels of <11 gm/dL within 1-week postdelivery define PPA.

*Rationale:* The UK guidelines, and Switzerland consensus statement, define PPA as an Hb level of <10 gm/dL.[24,27] However, the cut-off Hb value of below 11 gm/dL is recommended by the WHO. As per the WHO, PPA is defined as a Hb level of below 11 gm/dL at 1 week postdelivery and below 12 gm/dL in the 1-year postpartum.[28] The Network for the Advancement of Patient Blood Management, Hemostasis and Thrombosis (NATA), and French guidelines have recommended similar Hb cut-off values.[30] In consistent with these guidelines, other authors have used similar values.[1,7,31,32] Additionally, a cut-off value of below 11 gm/dL is routinely used in clinical practice. Given the fact that the majority of the women do not attain the required Hb levels during the antenatal period, they

tend to have reduced iron deposits despite normal Hb levels in the third trimester. Thus, PPA needs to be defined as Hb levels <11 gm/dL within a week postdelivery.

### *Statement 2*

Grading of PPA severity as mild, moderate, and severe with Hb levels of 10–10.9, 7–9.9, and below 7 gm/dL, respectively.

*Rationale:* In pregnant women, the WHO grades the anemia severity as mild, moderate, and severe with Hb levels of 10–10.9, 7–9.9, and below 7 gm/dL, respectively.[33] In India, good clinical practice recommendations have utilized a similar severity grade of anemia in pregnancy.[34] Similar grading of PPA severity is recognized by the NATA consensus statement.[35] Additionally, various studies from India have used PPA severity grading similar to that recommended by the WHO in pregnant women.[7,36] Thus, Hb cut-offs used for grading of anemia during pregnancy shall be used for grading of PPA.

### *Statement 3*

For early diagnosis and treatment of PPA, every PPW should be universally screened prior to discharge.

*Rationale:* As per the recent UK guidelines, women with uncorrected pregnancy anemia, those with >500 mL blood loss, or symptoms suggesting PPA should be screened.[27] Similar screening criteria are suggested by the Turkish consensus report.[25] Danish guidelines recommend Hb estimation for peripartum blood loss of more than 1000 mL.[37] Furthermore, current NATA and French consensus reports recommend Hb estimation in every woman with substantial peri-partum bleeding.[35] However, they did not quantify the substantial bleeding. Thus, Hb estimation criteria in PPW remain controversial. A recent study suggested increased diagnosis of anemia, particularly moderate-severe anemia, with routine screening of pregnant women for PPA and consequently improved patient care.[23] Even in developed countries, a high prevalence of PPA is observed in low-income women.[13] Additionally, universal screening should be taken up in high-prevalence settings, if resources are available.[22] Thus, considering the high prevalence of PPA in India, the health consequences, and the benefits of early diagnosis and treatment prior to discharge, universal Hb screening should be performed in every PPW.

### *Statement 4*

Universal Hb screening should be performed within 24–48 hours of delivery, prior to discharge.

*Rationale:* In the majority of women, PPA is caused by delivery-associated moderate-to-heavy blood loss, which leads to acute or subacute anemia, confirmed by Hb estimation 24–48 hours after delivery.[31] Similarly, the Turkish consensus report suggests that the Hb levels should be estimated within 24–48 hours of delivery.[25] Danish guidelines recommend Hb estimation within 24 hours.[37] As per the recent WHO guidelines, UK guidelines, Canadian guidelines, and NATA consensus report,[27,28,30,35] PPA should be diagnosed within 48 hours of birth. Though variation exists, all the available guidelines and consensus reports recommend early Hb estimation.

### *Statement 5*

In women with PPA, nonselective routine screening with serum ferritin (SF) is nonessential, and each PPW should be universally screened with Hb estimation and complete blood count (CBC).

*Rationale:* Serum ferritin levels are regarded as the surrogate marker of ID.[38] The levels decrease early during the development of ID and are not altered by iron intake.[35] Based on SF levels, ID can be classified as mild-moderate (<70–100 µg/L), and severe (<20–30 µg/L). Furthermore, ID is most likely absent if the SF levels are more than 100 µg/L.[38] Low SF has a good positive predictive value rather than a normal or high SF. Hence, adding SF estimation to Hb estimation seems to improve the sensitivity and pickup rate of anemia as many women may have normal HB levels but have depleted iron stores in the immediate PPP. Although reduced SF is suggestive of ID, SF, an acute phase reactant, may be raised out of proportion to iron stores due to inflammation, infection, malignancy, liver disease, or other factors. In these conditions, ID may be observed with normal or mildly raised SF levels.[39] Hence, though SF estimation appears to be appropriate for early estimation of anemia along with Hb estimation, nonselective screening with routine SF estimation is not advocated. Based on these findings and resource constraints, the Switzerland consensus statement does not recommend SF measurement in early PPP.[24] A similar view is held by the Turkish consensus report during the early PPP (first 6 weeks).[25] Additionally, nonselective screening with routine SF estimation is usually not recommended in the UK.[40]

Based on the findings mentioned in statements 3 and 4, early Hb estimation is required to screen the patients for PPA. A basic step in the IDA diagnosis requires consideration of the CBC, including Hb, mean corpuscular Hb, mean corpuscular volume and mean corpuscular Hb concentration. This is simple, economical, quick, and helpful for early IDA prediction.[26] Thus, universal screening with Hb and CBC should be performed before discharge.

### *Statement 6*

Ferric carboxymaltose is superior to oral and other intravenous (IV) iron therapies and all PPW should be discharged with a single dose of FCM after an informed decision.

*Rationale:* Parenteral iron therapy is preferred over oral due to poor patient compliance, intolerability, insufficient treatment response, and long duration of treatment associated with the latter. Additionally, IV iron therapy is preferred over intramuscular (IM) therapy. Intramuscular injection is associated with pain as well as chances of permanent skin staining, and the occurrence of gluteal sarcomas and sterile abscesses. Absorption of iron following IM therapy is slow and variable, with the inability to inject in patients with decreased muscle mass. It is not less toxic or safer compared to the IV route.[25] Moreover, for most of the patients, the required dose can be injected in a single visit, thus minimizing the frequent visits and ensuring better compliance and clinical outcomes.

A meta-analysis compared oral and IV iron therapy and reported that IV therapy is associated with raised Hb levels at 1, 2, and 3 weeks, and higher SF levels at 1, 2, 4, and 6 weeks in the PPP. At 6 weeks, the rise in Hb level was around 1 gm/dL more with the IV compared to the OI. Simultaneously, the adverse events such as dyspepsia and constipation were significantly less with the IV therapy. Therefore, IV iron is a superior choice for PPA.[41]

Ferric carboxymaltose has been demonstrated to have superior efficacy relative to OI in improving the Hb levels and attaining better iron stores. Additionally, FCM is reported to have a superior and sustained effect on the Hb relative to iron sucrose (IS). The improvement in Hb levels by ≥1 gm/dL was observed following a week and remained maintained after 6 weeks. Restoration of iron reserves as suggested by the improvement in SF levels was faster

① **Ferric carboxymaltose: 1 mL of solution contains 50 mg iron**

② **Determination of the iron need**

| Hb | | Patient body weight | | |
|---|---|---|---|---|
| gm/dL | mmol/L | <35 kg | 35 –<70 kg | ≥70 kg |
| <10 | <6.2 | 500 mg | 1500 mg | 2000 mg |
| 10–<14 | 6.2–<8.7 | 500 mg | 1000 mg | 1000 mg |
| ≥14 | ≥8.7 | 500 mg | 500 mg | 500 mg |

③ **Calculation and maximum individual iron dose(s)**

A single administration should not exceed:

- 15 mg iron/kg body weight (for administration by IV injection) or 20 mg iron/kg body weight (for administration by IV infusion)
- 1,000 mg of iron

The maximum recommended cumulative dose 1,000 mg of iron per week.

⑤ **Post-iron repletion assessments**

- Re-assessment should be performed by the clinician based on the individual patient's condition.
- The Hb level should be re-assessed no earlier than 4 weeks post final FCM administration to allow adequate time for erythropoiesis and iron utilization.
- In the event the patient requires further iron repletion, the iron need should be recalculated.

⑥ **Common adverse effects**

Hypophosphatemia, headache, dizziness, flushing, hypertension, nausea, injection/infusion site reactions.

⑦ **Watchout for**

- Signs and symptoms of hypersensitivity reactions for at least 30 minutes following each FCM administration.
- If hypersensitivity reactions occur, the treatment must be stopped immediately.
  - Facilities for cardio respiratory resuscitation and equipment for handling acute anaphylactic/anaphylactoid reactions should be available, including an injectable 1:1000 adrenaline solution.
  - Additional treatment with antihistamines and/or corticosteroids should be given as appropriate.

④ **Administration**

**IV injection**

FCM may be administered by IV injection using undiluted solution. The maximum single dose is 15 mg iron/kg body weight but should not exceed 1,000 mg iron.

**Administration rates for IV injection**

| Volume required | Equivalent iron dose | Administration rate/Minimum administration time |
|---|---|---|
| 2–4 mL | 100–200 mg | No minimal prescribed time |
| >4–10 mL | >200–500 mg | 100 mg iron/min |
| >10–20 mL | >500–1000 mg | 15 minutes |

**IV infusion**

FCM may be administered by IV infusion, in which case it must be diluted. Maximum single dose is 20 mg iron/kg body weight, but should not exceed 1,000 mg iron. For infusion, FCM must only be diluted in sterile 0.9% m/V sodium chloride solution.

**Dilution plan for IV infusion**

| Volume required | Equivalent iron dose | Max. sterile 0.9% m/V NaCl solution | Minimum administration time |
|---|---|---|---|
| 2–4 mL | 100–200 mg | 50 mL | No minimal prescribed time |
| >4–10 mL | >200–500 mg | 100 mL | 6 minutes |
| >10–20 mL | >500–1000 mg | 250 mL | 15 minutes |

**Fig. 1:** Ferric carboxymaltose administration

and more with FCM relative to IS and OI. Ferric carboxymaltose has a better safety profile relative to OI and IS.[42–50] As per the Anemia Mukt Bharat Programme, FCM or IS is the first choice for pregnant women diagnosed with anemia in late pregnancy or those with low compliance.[51] Ferric carboxymaltose infusions are reported to be more economical than IS infusions. Compared to IS, FCM is economical and leads to 30–44% savings per patient per treatment cycle[52] It is further reported that FCM is an economical and effective treatment option relative to red cell transfusion in women not responding to OI.[53] As opposed to IS, a test dose is not required with FCM, thus easing the administration of IV iron in a timely and economical manner.[38] Thus, in women with PPA, FCM should be preferred over oral and other IV iron therapies for rapid and effective correction of ID, replenishing iron reserves, and increasing Hb to normal levels. The specific information related to FCM administration is illustrated in Figure 1.[54,55]

In India, PPWs are usually discharged from healthcare facilities 48-hour postdelivery. This time period provides an excellent chance to treat PPA by injecting a single dose of FCM. Thus, the use of FCM 24–48 hours following childbirth could be very valuable to the healthcare systems as this would result in fewer hospital visits required to complete the doses and therefore, logistically more favorable to both the parties involved.

### *Statement 7*

Oral iron therapy is not required during or following FCM administration.

*Rationale:* As a rule, OI therapy needs to be continued for 6 weeks postpartum to fulfill the requirement and restore the iron deposits in the PPP.[56] However, considering the superior efficacy and safety profile, all required iron should ideally be replenished with FCM alone without the requirement of any OI therapy. A study assessed OI alone against FCM followed by OI for mild and moderate anemia, respectively, and reported identical Hb levels with significantly higher SF levels with combined treatment. It was further noticed that 20% and 52% of women in the OI alone group and the combination group, respectively did not even initiate oral treatment.[46] Although the resulting SF levels are favorable, we hypothesize that anemia correction with FCM monotherapy can swiftly and effectively improve Hb levels and restore iron deposits. When OI-associated GI intolerance is taken into consideration, FCM is the first choice for PPA correction. During the PPP, when the patient is in the hospital, attempts should be directed toward the administration of the single-dose FCM. Additionally, FCM should be used to meet all iron requirements and subsequent use of OI should be avoided. If required, in these patients, the decision to start oral therapy can be taken after 4 weeks of discharge.

### *Statement 8*

In all PPW, repeat Hb estimation should be performed at 6 weeks postdelivery.

*Rationale:* Postpartum period extends till 6 weeks following childbirth. Although the optimal timing for postpartum follow-up visits is not recognized, early postpartum care has been associated with reduced maternal and infant morbidity and improved patient satisfaction.[57] The WHO recommends that postpartum care should include routine assessment of the mother and newborn at 3 days, 7–14 days, and 6 weeks.[58] The WHO further recommends that OI therapy may be given to PPW for 6–12 weeks postdelivery and women with PPA should be treated with daily iron (with folic acid)

supplements until Hb reaches normal levels.[28] In women with mild-moderate PPA, other guidelines also recommend the continuation of iron supplements for 3 months.[25,27,35] Additionally, 6 weeks is the appropriate time for iron supplements to replenish the iron stores. Thus, the first follow-up visit at 6 weeks is an excellent opportunity to assess the effect of treatment by re-estimating the Hb levels.

## Conclusion

In PPP, IDA adversely affects both maternal and neonatal health. For early diagnosis and treatment of PPA, all PPW should be routinely screened for PPA with Hb and CBC within 24–48 hours postdelivery, prior to discharge. Available evidence suggests that FCM is a safe, effective, well-tolerated, and economical option for managing PPA compared to OI and IS. With a growing recommendations generated based on the clinical evidence, FCM appears to be a preferred choice for all severities of PPA. To enhance postdelivery care of PPW with convenience to both the patients and healthcare professionals, all PPW should be discharged with a single dose of FCM after informed decision and consent by the patient and should be preferred over OI and IS to swiftly raise the Hb levels and replenish the iron deposits with greater safety. Within 6 weeks of treatment, the Hb levels increase significantly with a significant rise in SF and replenishment of iron deposits. Thus, repeat Hb estimation should be performed at 6-week follow-up visit.

### Summary of Consensus

- The cut-off Hb levels of below 11 gm/dL within 1-week postdelivery defines PPA.
- Grading of PPA severity as mild, moderate, and severe with Hb levels of 10–10.9, 7–9.9, and below 7 gm/dL, respectively, and this is similar to Hb cut-offs used for grading of anemia during pregnancy.
- For early diagnosis and treatment of PPA, every PPW should be universally screened prior to discharge.
- Universal Hb screening should be performed within 24–48 hours of delivery, prior to discharge.
- In women with PPA, unselected routine screening with SF is nonessential, and each PPW should be universally screened with Hb estimation and CBC.
- Injection FCM is superior to oral and other IV iron therapies and all PPW should be discharged with a single dose of FCM after the informed decision.
- OI therapy is not required during or following FCM administration and the decision to start oral therapy can be taken after 4 weeks of discharge, if required.
- In all PPW, repeat Hb estimation should be performed at 6 weeks postdelivery.

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## Orcid

*Shantha Kumari Sekaran* https://orcid.org/0009-0005-3156-4268
*Reena Wani* https://orcid.org/0000-0002-4670-7437

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