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Clinical Audit of Prescribing Administration and Monitoring of Intravenous Ferric Carboxymaltose in an University Hospital Kerry

[1] Khalid Ghalib, [2] Catriona O'Sullivan, [3] Mauora O'Connor, [4] Mazin Mohamed, [5] Jose Rani, [6] Almeera Mujahid, [7] Sara Abuelbashar, [8] Lena Hamza, [9] Khalid Elgalal, [10] Sahar Abdalla, [11] Ola Abuzeid, [12] Samra Saleem, [13] Ambreen Naz, [14] Zeeshan Alam, [15] Kevin Hii, [16] Khawla Anis, [17] Abuzer Ali, [18] Mohammed Ali, [19] Yousif Elnour, [20] Ihtisham Malik

[1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20] Department of Pharmacy, Kerry University Hospital, Tralee, Co.Kerry, Ireland

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Corresponding Author: **Khalid Galib**

Abstract

Background: Iron-deficiency anaemia is common and clinically important. Intravenous ferric carboxymaltose permits rapid iron replacement when oral iron is ineffective, not tolerated or unsuitable, but safe use depends on documented indication, weight- and haemoglobin-informed dosing, appropriate dose intervals, precautions, administration monitoring and follow-up.

Objective: To evaluate compliance with evidence-based and product-information standards for ferric carboxymaltose prescribing, administration and monitoring in adults at University Hospital Kerry.

Methods: A prospective clinical audit included 53 consecutive eligible adult inpatient, day-case and ambulatory-care episodes from 9 to 20 July 2026. Twelve criteria derived from local policy, the Summary of Product Characteristics and relevant guidance were assessed from medical records, prescriptions, administration records and laboratory systems. Results are reported as proportions with Wilson 95% confidence intervals.

Results: Laboratory confirmation of iron deficiency and monitoring during or after administration were documented in 53/53 episodes (100% each). Avoidance of ferric carboxymaltose in anaemia not attributable to iron deficiency and compliance with the licensed maximum dose were each achieved in 46/53 (86.8%). Documentation was lower for indication (40/53, 75.5%), investigation or documentation of the underlying cause (36/53, 67.9%), planned follow-up (33/53, 62.3%), review of contraindications and precautions (30/53, 56.6%) and consideration of phosphate monitoring (30/53, 56.6%). Only 20/41 applicable repeat-dose episodes (48.8%) met the minimum 7-day interval. Body weight was documented in 7/53 (13.2%), and total iron requirement was calculated and documented in 3/53 (5.7%).

Conclusion: The audit identified reliable laboratory confirmation and peri-administration monitoring but major weaknesses in traceable individualised dosing, repeat-dose timing and follow-up planning. A standardised request and prescription form with mandatory weight, haemoglobin, indication, dose calculation, interval, risk-based phosphate assessment and follow-up fields is the principal improvement intervention. Re-audit after implementation is required to determine its effect.

Keywords: Anaemia, Iron Deficiency, Ferric Carboxymaltose, Intravenous Iron, Medication Safety, Clinical Audit, Quality Improvement, Hypophosphataemia

Introduction

Anaemia is a reduction in blood haemoglobin concentration below an accepted threshold for age, sex and physiological state. It reduces oxygen-carrying capacity and may cause fatigue, exertional dyspnoea, impaired cognition and reduced functional capacity. Iron deficiency is among the most frequent causes of anaemia, but it is also clinically relevant before anaemia develops. In adults, deficiency may reflect inadequate intake, impaired absorption, increased physiological requirement, chronic inflammation or ongoing blood loss. Identification and treatment of the underlying cause are therefore integral to management rather than optional additions to iron replacement [1-3].

Oral iron is generally first-line therapy when it is likely to be absorbed and tolerated. Intravenous iron is appropriate when oral

treatment is contraindicated, ineffective or poorly tolerated; when malabsorption or continuing blood loss makes oral replacement unlikely to succeed; or when rapid correction is clinically necessary [2, 3]. Ferric carboxymaltose is a non-dextran intravenous iron complex that enables administration of relatively large iron doses over a short period. Its convenience does not remove the need for accurate patient selection and dosing. The authorised product information requires confirmation of iron deficiency by laboratory tests, calculation of the cumulative iron requirement using haemoglobin and body weight, adherence to maximum single and weekly doses, and spacing of additional doses by at least seven days [4].

Intravenous iron can cause hypersensitivity reactions and administration-related adverse effects. Ferric carboxymaltose is also associated with hypophosphataemia, mediated largely through increased biologically active fibroblast growth factor 23 and renal phosphate wasting. Repeated exposure, high cumulative doses and pre-existing risk factors may lead to symptomatic hypophosphataemia, osteomalacia and fractures; regulators therefore recommend serum phosphate monitoring in patients receiving multiple high-dose or long-term treatment and in those with relevant risk factors [5-7]. These risks make reliable documentation, prospective safety checks and planned follow-up important components of medication governance.

Routine multidisciplinary review at University Hospital Kerry identified variation in ferric carboxymaltose prescribing and monitoring. This audit was undertaken to measure baseline compliance, identify the highest-priority process gaps and inform a practical quality-improvement intervention.

Aim

The aim was to evaluate compliance with evidence-based standards for prescribing, administration and monitoring of ferric carboxymaltose in adult patients at University Hospital Kerry and to identify opportunities to improve patient safety and prescribing quality.

- Assess whether ferric carboxymaltose was used for an appropriate and documented indication.
- Assess whether the iron requirement and prescribed dose were determined from documented body weight and haemoglobin in accordance with the product information.
- Assess compliance with authorised administration limits, minimum repeat-dose intervals and peri-administration monitoring.
- Assess documentation of precautions, phosphate risk assessment and follow-up.
- Use the findings to define a feasible intervention and re-audit plan.

Method

Design and setting

This was a prospective, single-centre baseline clinical audit conducted at University Hospital Kerry, an acute hospital in Ireland.

Eligibility and sampling

Eligible episodes were adults receiving ferric carboxymaltose as an inpatient on a medical or surgical service, as a day case or through ambulatory care during the audit period. Paediatric patients, patients receiving another intravenous iron formulation and records without sufficient access for assessment were excluded. Consecutive eligible episodes were reviewed. The achieved sample was 53, within the prespecified operational target of 50–60 episodes.

Audit criteria and data sources

The multidisciplinary audit team reviewed medical records, medication and prescription charts, infusion administration records and the laboratory information system. Twelve process criteria were derived from local policy, the ferric carboxymaltose Summary of Product Characteristics and relevant guidance. Each criterion was coded as compliant or non-compliant. For the repeat-dose interval criterion, the denominator was restricted to episodes in which a repeat dose was applicable (n=41); other reported criteria used the full denominator (n=53).

Audit criterion	Expected standard	Operational evidence of compliance
Indication documented	100%	Clinical indication recorded in the available record
Iron deficiency confirmed	100%	Relevant baseline laboratory evidence, including haemoglobin and ferritin and/or transferrin saturation
Underlying cause addressed	100%	Cause investigated or documented
Body weight documented	100%	Weight available for dose calculation
Total iron requirement documented	95–100%	Cumulative dose calculated from haemoglobin and weight according to product information
Licensed maximum dose respected	100%	Single and weekly dose limits not exceeded
Contraindications and precautions reviewed	100%	Documented safety review before administration
Phosphate monitoring considered	100%	Risk-based consideration or measurement documented
Minimum repeat-dose interval	100%	At least seven days between applicable doses
Peri-administration monitoring	100%	Observation during and after administration documented
Follow-up plan	90–100%	Repeat laboratory tests and/or clinical review planned after treatment
Avoided in non-iron-deficiency anaemia	100%	No treatment where available evidence did not support iron deficiency

Analysis

Analysis was descriptive.

Results

Included episodes

Fifty-three eligible ferric carboxymaltose treatment episodes were audited. The available source report did not contain age, sex, clinical specialty, indication distribution, haemoglobin, ferritin, transferrin saturation, phosphate concentration or adverse-event summaries; these cannot be reported without returning to the source dataset.

Compliance with audit criteria

Table 1: Compliance with ferric carboxymaltose audit criteria. Confidence intervals are Wilson intervals and are descriptive

Criterion	Compliant	Total	Compliance	95% CI
Laboratory confirmation of iron deficiency	53	53	100.0%	93.2–100.0%
Monitoring during and after administration	53	53	100.0%	93.2–100.0%
Avoidance in non-iron-deficiency anaemia	46	53	86.8%	75.2–93.5%
Compliance with licensed maximum dose	46	53	86.8%	75.2–93.5%
Documented indication for intravenous iron	40	53	75.5%	62.4–85.1%
Underlying cause investigated or documented	36	53	67.9%	54.5–78.9%
Follow-up blood tests or review planned	33	53	62.3%	48.8–74.1%
Contraindications and precautions reviewed	30	53	56.6%	43.3–69.0%
Phosphate monitoring considered	30	53	56.6%	43.3–69.0%
Minimum 7-day repeat-dose interval maintained	20	41	48.8%	34.3–63.5%
Body weight documented	7	53	13.2%	6.5–24.8%
Total iron requirement calculated and documented	3	53	5.7%	1.9–15.4%

Full compliance was achieved for laboratory confirmation of iron deficiency and monitoring during and after administration (53/53, 100% each). Compliance with the licensed maximum dose and avoidance of treatment in anaemia not attributable to iron deficiency were each 46/53 (86.8%). Indication was documented in 40/53 episodes (75.5%), and the underlying cause was investigated or documented in 36/53 (67.9%).

Follow-up testing or review was planned in 33/53 episodes (62.3%). Contraindications and precautions were reviewed in 30/53 (56.6%), and phosphate monitoring was considered in 30/53 (56.6%). Among 41 episodes in which repeat-dose timing was applicable, 20 (48.8%) met the minimum seven-day interval. The lowest compliance was for body-weight documentation (7/53, 13.2%) and calculation and documentation of the total iron requirement (3/53, 5.7%).

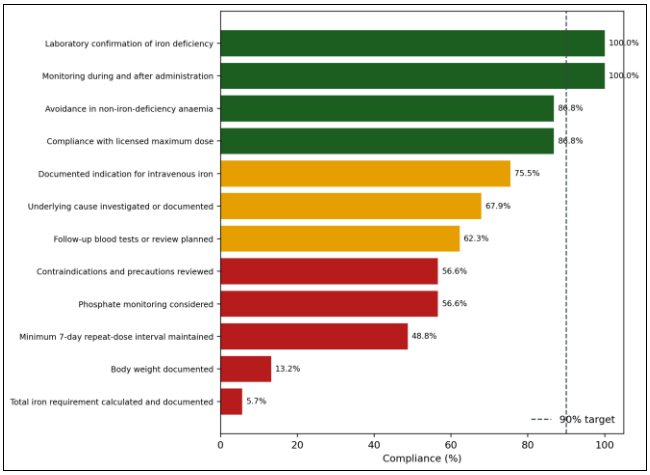

Fig 1: Compliance across 12 audit criteria. Green indicates at least 85%, amber 60–84% and red below 60%. The dashed line is the 90% target

Discussion

Principal findings

This audit found two dependable parts of the pathway: laboratory confirmation of iron deficiency and monitoring during and after administration. However, the records frequently lacked the information needed to demonstrate that treatment had been individualised and safely sequenced. In particular, only one in eight episodes included documented body weight and fewer than one in 17 included a documented total iron calculation. Nearly half of applicable repeat-dose episodes did not meet the documented seven-day interval standard. Documentation of indication, investigation of the cause, safety review, phosphate consideration and follow-up planning was also incomplete.

Interpretation in relation to evidence and guidance

The dosing findings are clinically important because authorised ferric carboxymaltose dosing depends on haemoglobin and body weight, with limits on single and cumulative weekly exposure [4]. Absence of documentation does not prove that an incorrect dose was administered, but it prevents independent verification and weakens continuity of care. The appropriate interpretation is therefore a failure of traceability and dose assurance, with a plausible risk of under-replacement, overexposure or incorrectly timed repeat treatment.

Investigation of the cause of iron deficiency was documented in approximately two thirds of episodes. Guidelines emphasise that iron replacement and causal investigation should proceed together when appropriate, particularly because occult gastrointestinal or gynaecological blood loss, coeliac disease, malabsorption, chronic kidney disease and inflammatory disorders may require additional management [2, 3]. A structured pathway should prompt the prescriber to state both the biochemical diagnosis and the likely or confirmed cause, or to document the plan for further investigation.

Phosphate monitoring was considered in 56.6% of episodes. Universal phosphate measurement is not necessarily required for every patient, but a documented risk assessment is important. Regulatory advice and clinical evidence identify repeated high-dose exposure, long-term use and risk factors for hypophosphataemia as reasons for monitoring [5-7]. The audit criterion should therefore be implemented as risk-based assessment rather than indiscriminate testing.

Follow-up was planned in 62.3% of episodes. The ferric carboxymaltose product information advises reassessment of haemoglobin no earlier than four weeks after the final dose, allowing time for erythropoiesis and iron utilisation [4]. Failure to schedule reassessment may lead to missed non-response, persistent blood loss, recurrent deficiency or unnecessary retreatment.

Proposed quality-improvement intervention

The main intervention is a standardized ferric carboxymaltose request and prescription form embedded in the existing workflow. A single structured form could address several linked failure points and reduce reliance on free-text documentation. The form should require patient identifiers, indication and suspected cause; current weight and haemoglobin; ferritin and/or transferrin saturation;

contraindication and precaution review; risk-based phosphate assessment; calculated total iron requirement; proposed dose, route, dilution and rate; date of any prior dose; an automatic or manual seven-day interval check; peri-administration observation; and a dated follow-up plan. Pharmacist verification of the calculation before administration should be included where operationally feasible.

Implementation should be supported by brief prescriber and nursing education, ready access to weighing equipment, clear ownership of follow-up and prospective feedback. A balancing measure should assess whether the form delays clinically necessary treatment or adds avoidable workload. Re-audit using the same definitions and denominators is proposed three months after implementation. The primary improvement measures should be documented weight, documented total dose calculation, compliant repeat-dose interval and documented follow-up.

Strengths and limitations

Strengths include prospective consecutive case ascertainment, multidisciplinary review, inclusion of inpatient and ambulatory pathways, use of explicit process standards and reporting of exact numerators and denominators. The audit also identified a focused intervention directly linked to the observed gaps.

The study has important limitations. It was conducted at one hospital over 12 days and included 53 episodes, limiting precision and generalisability. The unit of analysis was a treatment episode; the source report did not establish whether any patient contributed more than one episode. Several criteria measured documentation, which may underestimate actions performed but not recorded. The audit did not report patient characteristics, clinical indications, adverse reactions, phosphate outcomes, haemoglobin response, readmission or other clinical outcomes. The repeat-dose criterion used an applicable denominator of 41, while other criteria used 53. Finally, this baseline audit cannot show that the proposed form improves practice; a completed re-audit is required.

Conclusion

At this acute Irish hospital, ferric carboxymaltose use showed complete documentation of laboratory confirmation and peri-administration monitoring, but major gaps in documented body weight, cumulative iron calculation, repeat-dose timing, safety assessment and follow-up planning. A structured request and prescription form, supported by multidisciplinary education and pharmacist verification, is a proportionate intervention. Re-audit should determine whether it improves reliable, traceable and guideline-concordant care.

Declarations

Ethics and governance: UHK policy for Audit and QIP applied.

References

1. World Health Organization. Guideline on haemoglobin cutoffs to define anaemia in individuals and populations. Geneva: World Health Organization, 2024.
2. Camaschella C. Iron-deficiency anemia. N Engl J Med. 2015; 372(19):1832-1843. Doi: 10.1056/NEJMra1401038
3. Snook J, Bhala N, Beales ILP, *et al*. British Society of Gastroenterology guidelines for the management of iron deficiency anaemia in adults. Gut. 2021; 70(11):2030-2051. Doi: 10.1136/gutjnl-2021-325210
4. Vifor Pharma UK Ltd. Ferinject 50 mg iron/mL solution for injection/infusion: Summary of Product Characteristics. Electronic Medicines Compendium. Accessed October 13, 2026. https://www.medicines.org.uk/emc/product/5910/smpc.
5. Medicines and Healthcare products Regulatory Agency. Ferric carboxymaltose (Ferinject): Risk of symptomatic hypophosphataemia leading to osteomalacia and fractures. Drug Safety Update. November 16, 2020.
6. Wolf M, Chertow GM, Macdougall IC, Kaper R, Krop J, Strauss W. Randomized trial of intravenous iron-induced hypophosphatemia. JCI Insight. 2018; 3(23):e124486. Doi: 10.1172/jci.insight.124486
7. Schaefer B, Tobiasch M, Viveiros A, *et al*. Hypophosphataemia after treatment of iron deficiency with intravenous ferric carboxymaltose or iron isomaltoside: A systematic review and meta-analysis. Br J Clin Pharmacol. 2021; 87(5):2256-2273. Doi: 10.1111/bcp.14643
8. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised publication guidelines from a detailed consensus process. BMJ Qual Saf. 2016; 25(12):986-992. Doi: 10.1136/bmjqs-2015-004411
9. Pasricha SR, Tye-Din J, Muckenthaler MU, Swinkels DW. Iron deficiency. Lancet. 2021; 397(10270):233-248. Doi: 10.1016/S0140-6736(20)32594-0
10. Auerbach M, Macdougall IC. Safety of intravenous iron formulations: Facts and folklore. Blood Transfus. 2014; 12(3):296-300. Doi: 10.2450/2014.0094-14
11. Evstatiev R, Marteau P, Iqbal T, *et al*. FERGIcor, a randomized controlled trial on ferric carboxymaltose for iron deficiency anemia in inflammatory bowel disease. Gastroenterology. 2011; 141(3):846-853.e2. Doi: 10.1053/j.gastro.2011.06.005
12. European Medicines Agency. New recommendations to manage risk of allergic reactions with intravenous iron-containing medicines. London: EMA, 2013.