Appropriate Use of Inpatient Erythropoiesis Stimulating Agents

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Abstract
Background: Anemia is a significant global public health issue, and is associated with lethargy, weakness, tiredness, and shortness of breath. Erythropoiesis stimulating agents (ESAs) are recombinant/synthetic erythropoietin and can increase hemoglobin (Hb) levels. There are increased risks of cardiovascular events and death associated with the use of ESAs when raising Hb levels above 12 g/dL. *Methods:* The objective was to assure safety and appropriate use of ESA. We performed a baseline assessment via a retrospective chart review, including patients who recently received an inpatient dose of an ESA within Mount Sinai Hospital (MSH) from November 1, 2015 (after MSH ESA guideline revision) to August 1, 2023. All adult patients who received an ESA (originator or biosimilar products) during hospitalization were included. Data collection was in reverse chronology, and the most recent dose administered to each unique patient was collected. *Results*: If an ESA dose was dispensed when the Hb was less than the upper limit of the target Hb for the specific indication, this was considered appropriate use. Based on data from June 15 to August 1, 2023 (~47 days of inpatient utilization), for the primary outcome, 169 out of 171 doses (98.8%) met the predefined criteria for appropriateness. One dose was dispensed when the Hb was 11.1 g/dL to a patient on renal replacement therapy, and one dose was dispensed when the Hb was 13.8 g/dL to a surgical patient who refused blood transfusions. Among secondary outcomes of interest, there was a difference in blood transfusions administered in critical versus non-critical care settings. *Conclusion*: Inpatient use of ESA at MSH was appropriate when looking at Hb targets. There are currently no formal order sets, service-line restrictions, or additional chairperson approvals needed at MSH. Despite this, there remained significant adherence to prevailing Hb targets, reflecting provider and pharmacy teams' knowledge and awareness of contemporary best practices.

Keywords: Anemia, erythropoiesis stimulating agents, erythropoietin

Background

Anemia is a significant global public health issue that affects approximately 3 million people in the United States.[1] Anemia is defined as hemoglobin (Hb) less than 13 g/dL in males and less than 12 g/dL in females.[2] The primary etiologies of anemia include blood loss/hemolysis or deficient/defective erythropoiesis, iron deficiency, vitamin deficiency, and others.[2-4] Complications of anemia, especially when Hb is less than 7 g/dL, can include lethargy, weakness, tiredness, shortness of breath, reduced exercise tolerance, angina, worsening heart failure, and left ventricular hypertrophy.[2,3,5]

Erythropoietin (EPO) is a glycoprotein hormone produced mostly by the kidney (renal cortex peritubular cells) that stimulates red blood cell proliferation.[2-5] EPO levels are lower in kidney diseases.[2-5] Erythropoiesis stimulating agents (ESAs) are recombinant/synthetic EPO that can improve anemia, and available products are listed in **Table 1**.[6,7] However, due to increased risks of cardiovascular events and death, ESAs should be avoided if the Hb is 12 g/dL or higher.[6,7]

The Mount Sinai Hospital (MSH) is a large academic medical center and its ESA guideline from October 2015, as summarized in **Table 2**, contains information related to clinical monitoring of specific indications and respective Hb goals.[8] Of note, there was an ESA APPRISE REMS program for oncology indications for several years, but the FDA discontinued it after April 2017.[9] This guideline did not imply service or order restrictions, and it has not been systematized via a clinical order set yet.

Current literature on ESA utilization has varying populations, methods, and outcomes of interest, as summarized in **Table 3**.[17-22] Patel (2020), Buckley (2013), and Kimura (2004) analyzed inpatient populations.[17,20,22] Most recently, Patel (2020) examined 54 non-critical care hospitalized patients who received a total of 167 doses over a 2-week period: 93% for chronic kidney disease (CKD) on hemodialysis (HD), 4% with CKD not on HD, 2% for chemotherapy-induced anemia (CIA), and 1% for acute kidney injury (AKI).[17] They mentioned that all ESA doses were prescribed in congruence with indications and hemoglobin levels, with 95% prescribed via a clinical order set.[17] Of note, Patel (2020) reported one patient who apparently received 69 doses during hospitalization (which could have skewed 41% of the dose outcomes) and the other 53 patients received the remaining 98 doses (with a reported mean of 7 doses per patient, but a reported median would have mitigated outlier influence and have been closer to 1-2 doses per patient).[17]

Objective

The primary endpoint of this study was related to a baseline safety assessment, specifically the appropriateness of inpatient

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ESA based on Hb targets defined in the prevailing MSH ESA guideline. **Table 4** further clarifies these indications, respective targets, and definitions of appropriateness. We collected additional information for comprehensiveness, including differences among critical care and non-critical care settings, recent RBC transfusions, Epic I-vents (pharmacy documentations), EPO levels, concurrent supplementation (i.e., iron, B12, folate) for anemia, venous thromboembolism (VTE) prophylaxis, and anemia panel results (for iron, ferritin, TSAT, TIBC, B12, and folate).

Methods

This was a retrospective chart review (non-interventional comparative cohort study) including patients who recently received an inpatient dose of ESA within MSH from November 1, 2015 (after MSH ESA guideline revision) to August 1, 2023. This study was approved by the Institutional Review Board (IRB). All adult patients (age 18 years and older) who received ESA (originator or biosimilar products) during hospitalization were included.

There were 4 cohorts based on the primary indication for ESA:

1) CKD without renal replacement therapy (RRT);
2) RRT including HD, peritoneal dialysis (PD), and continuous renal replacement therapy (CRRT);
3) Oncology including chemo-induced anemia (CIA) and myelodysplastic syndrome (MDS); and
4) other indications including surgery, refusal of blood transfusions, and HIV-related anemia.

With a focus on the latest trends, data collection was in reverse chronology, and only the most recent dose administered to each unique patient was collected. There was a goal to collect data for 100 doses per cohort, with a total sample size of 400.

Results (Tables 5 to 9)

Results in **Tables 5 to 9** reflected data from June 15 to August 1, 2023 (~47 days of inpatient utilization). To better assess contemporary practice, there was a focus on reverse chronology or the latest trends, instead of random sampling over the study period. For the primary outcome (**Table 6**), 169 out of 171 doses (98.8%) met the predefined criteria for appropriateness (**Table 4**). In the RRT group, 1 dose was dispensed when the Hb was 11.1 g/dL. In the Other group, 1 dose was dispensed when the Hb was 13.8 g/dL; this patient had refused blood transfusion support and needed coronary artery bypass graft surgery (CABG). In these 2 cases, ESA was dispensed despite the Hb exceeding the upper limit of the target range, but there was no associated pharmacy I-vent. There was no progress note documentation of any adverse event in these 2 cases. **Tables 7 to 9** provide additional information regarding critical care and non-critical care settings, laboratory testing, and concomitant medications. This provided us with a comprehensive understanding of ESA utilization. There was a statistical difference in RBC transfusions administered in critical versus non-critical care settings, which was an expected finding because it appeared consistent with standard practice in each setting. Future projects can potentially include deeper assessments of anemia diagnoses, laboratory timepoints and interpretations, and concurrent drug management.

Aside from standard order entry elements of dose, route, frequency, product, and dispense location, current ordering screens additionally display 3 recent Hb values. There are currently no formal order sets, service-line restrictions, or additional chairperson approvals needed at MSH. Despite this, there remained significant adherence to prevailing Hb targets, reflecting provider and pharmacy teams' knowledge and awareness of contemporary best practices.

In contrast to ESA, there are unique procedures at MSH for another product: granulocyte colony-stimulating factor (G-CSF)/filgrastim. This drug requires service line approvals upon order entry, precise timing or spacing from myelosuppressive chemotherapy, pharmacy I-vent documentation for each dispense, and ongoing re-evaluation for discontinuation once absolute neutrophil count (ANC) targets are met. Based on our findings, there does not seem to be an acute need at MSH to start requiring the same elements as G-CSF as part of the prescribing or dispensing processes yet, but this may be revisited in the future.

Limitations

There were limitations to this retrospective chart review. The goal number of doses was achieved for the RRT group, but most data was descriptive (instead of inferential). This was also interpreted as a reflection of the relative practice differences for inpatient ESA utilization, driven mostly by nephrology (RRT, CKD), then surgery, and finally oncology. For situations where there was a potential overlap of services and indications for ESA (e.g., oncology and CKD), there was a re-review of progress notes to determine the primary indication.

We reviewed the most recently administered dose for assessment of prescribing trends. While this did not capture patients who received multiple doses, the methodology still provided us with assurance that ESAs were being used safely. The appropriateness of use was based on clinical practice guidelines and published literature. We did not make case-specific clinical judgments or require multiple rounds of review to determine appropriate use; we considered this approach to be acceptable among our various practice settings.

Conclusion

Overall, this research demonstrated that inpatient use of ESA at MSH was appropriate when looking at Hb targets, despite minimal order restrictions (i.e., no dose or service limitations) and the current lack of a systematized clinical order set. ESA

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utilization within critical care or step-down units appeared to be driven by patients with RRT needs. We learned more about our safe prescribing practices and trends, reflecting our inpatient provider and pharmacy teams' knowledge and awareness. Future projects can provide greater insights into anemia diagnoses, laboratory timepoints and interpretations, and concurrent drug management.

Conflicts of Interest: None to disclose.

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Table 1. Available erythropoiesis stimulating agent products[6,7]

Product	Initial FDA Approval	Manufacturer(s)	MSH Formulary
epoetin alfa (EPOGEN®, PROCRIT®)	1989	Amgen, Janssen	Yes
epoetin alfa - epbx (RETACRIT®)	2018	Pfizer / Hospira	Yes
darbepoetin alfa (ARANESP®)	2001	Amgen	Restricted to ambulatory care
methoxy polyethylene glycol - epoetin beta (MIRCERA®)	2007	Roche	No

FDA = US Food and Drug Administration;
MSH = The Mount Sinai Hospital

Table 2. Summary of current MSH ESA guideline from October 2015[8,10-16]

Indication	Criteria for Starting ESA	Hb Target (g/dL)	Initial Dosing of ESA	Additional Monitoring Parameters
CKD, ESKD on HD	Hb < 10 g/dL, or Hb 10 to < 11 g/dL & symptomatic	9 to 11 (KDIGO)	50-100 units/kg, SC or IV, three times per week	iron, B12, ferritin, TSAT, TIBC
CIA	Hb < 10 g/dL & non-curative chemotherapy intent	< 10 (NCCN)	10,000 units (or 150 units/kg), SC, three times per week	iron, B12, ferritin, TSAT, TIBC, folate
MDS	serum EPO ≤ 500 mU/mL & Hb < 10 g/dL or symptomatic Hb < 11 g/dL	10 to 12 (NCCN)	40,000 units, SC, once per week	iron, B12, ferritin, TSAT, TIBC, folate
HIV-related anemia	Consult HIV medicine & hematology, EPO ≤ 500 mU/mL	8 to 10 (Henry; Volberding)	100 units/kg, SC, three times per week	iron
Critical care	Hb ≤ 9 g/dL	7 to 9 (Corwin)	*(N/A - increased VTE risk and hospitalization duration with trauma patients; did not reduce RBC transfusions in critically ill)*	VTE prophylaxis
Surgery	Hb > 7 to ≤ 9 g/dL, or RBC transfusion refusal	12 to 13 (Kozek)	300 unit/kg, SC, daily (day -10 to +4), or 600 unit/kg, SC, once per week (day -21, -14, -7, 0)	N/A

CIA = chemotherapy-induced anemia;
CKD = chronic kidney disease;
EPO = erythropoietin;
ESA = erythropoiesis stimulating agent;
ESKD = end-stage kidney disease;
HD = hemodialysis;
Hb = hemoglobin;
HIV = human immunodeficiency virus;
IV = intravenous;
MDS = myelodysplastic syndrome;
MSH = The Mount Sinai Hospital;
RBC = red blood cell;
SC = subcutaneous;
TIBC = total iron binding capacity;
TSAT = transferrin saturation;
VTE = venous thromboembolism

Table 3. Select literature summary of ESA utilization[17-22]

Citation	Design	Location	Population	Outcomes
Patel (2020)	Retrospective chart review	Massachusetts General Hospital, MA	Inpatient Non-ICU	86% (n = 144) were utilized in accordance with guideline-based assessment criteria regarding laboratory monitoring of iron studies.
Weil (2015)	Retrospective chart review	Medical College, WI	Outpatient MDS & CIA	In the post-implementation group, all patients had hemoglobin levels drawn, 16.67 % did not have iron studies completed, and all MDS patients had EPO levels drawn appropriately.
Debenito (2014)	Retrospective chart review	Kaiser Permanente, CO	Outpatient CKD without HD	Pharmacist-managed patients had improved adherence to guidelines for Hb monitoring (32.3% vs. 14.3%, p = 0.049) and iron monitoring (61.3% vs. 30.0%, p = 0.005) compared with similar patients.
Buckley (2013)	Retrospective chart review	Banner University Medical Center, AZ	Inpatient	Proportion of patients prescribed ESA was significantly smaller after guideline implementation (2.4% vs 1.6%; p < 0.001); the reduction in the total number of ESA doses administered was 45%.
Aspinall (2012)	Retrospective chart review	10 Veterans Affairs Medical Centers, USA	Outpatient CKD without HD	More Hb values were in the target range in pharmacist-managed ESA clinics (71.1% vs 56.9% for usual-care sites; p < 0.001).
Kimura (2004)	Retrospective chart review	Tokushukai Nozaki Hospital, Japan	Inpatient ESKD on HD	Hematocrit >30% was more achieved with pharmacist intervention, from 7/41 (17%) to 32/41 (78%). Also, 23/41 (56%) decreased their ESA dose and 5/41 (12%) could stop ESA therapy.

CIA = chemotherapy-induced anemia;
CKD = chronic kidney disease;
EPO = erythropoietin;
ESA = erythropoiesis stimulating agent;
ESKD = end-stage kidney disease;
HD = hemodialysis;
ICU = intensive care unit;
MDS = myelodysplastic syndrome

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Table 4. Defining the primary outcome of appropriate use[6,7]

Indication	Hb Target (g/dL)	Appropriate Hb (g/dL) for inpatient ESA use
CKD, or ESKD on HD	9 to 11	≤ 11
CIA	< 10	< 10
MDS	10 to 12	≤ 12
HIV-related anemia	8 to 10	≤ 10
Critical care	7 to 9	≤ 9
Surgery	12 to 13	≤ 13

CIA = chemotherapy-induced anemia;
CKD = chronic kidney disease;
ESA = erythropoiesis stimulating agent;
ESKD = end-stage kidney disease;
HD = hemodialysis;
Hb = hemoglobin;
HIV = human immunodeficiency virus;
MDS = myelodysplastic syndrome

Table 5. Baseline characteristics

	CKD (n = 27)	RRT (n = 100)	Oncology (n = 6)	Other (n = 38)
Age, years, median (range, IQR)	62 (18-91, 45-76)	63 (18-91, 51-69)	66 (58-81, 59-71)	63 (20-84, 54-73)
Gender, n (%)				
Male	15 (55.6%)	47 (47%)	3 (50%)	20 (52.6%)
Female	12 (44.4%)	53 (53%)	3 (50%)	18 (47.4%)
Race, n (%)				
White	7 (25.9%)	18 (18%)	2 (33.3%)	14 (36.8%)
Black	8 (29.6%)	38 (38%)	3 (50%)	4 (10.5%)
Hispanic	-	1 (1%)	-	-
Asian	4 (14.8%)	4 (4%)	-	2 (5.3%)
Other or Unknown	8 (29.6%)	39 (39%)	1 (16.7%)	18 (47.4%)
Renal Function				
Serum Creatinine, mg/dL, median (range, IQR)	2.24 (1.1-6.8, 1.8-3.4)	4.53 (0.8-24.3, 2.6-7)	1.54 (0.8-3.4, 1-1.9)	0.97 (0.4-2.38, 0.7-1.3)
eGFR, mL/min/1.73 m2, median (range, IQR)	26 (8-69, 20-40)	-	44 (20-86, 31-73)	81 (23-137, 59-99)
CKD Stage				
1 (eGFR >90)	1 (3.7%)	-	-	16 (42.1%)
2 (eGFR 60-89)	1 (3.7%)	-	2 (33.3%)	12 (31.6%)
3A (eGFR 45-59)	2 (7.4%)	-	1 (16.7%)	3 (7.9%)
3B (eGFR 30-44)	7 (25.9%)	-	1 (16.7%)	6 (15.8%)
4 (eGFR 15-29)	12 (44.4%)	-	2 (33.3%)	1 (2.6%)
5 (eGFR <15)	4 (14.8%)	-	-	-
RRT Modality				
HD	-	98 (98%)	-	-
PD	-	2 (2%)	-	-
Body Weight, kg, median (range, IQR)	82.1 (36.7-123.4, 60.9-103.5)	65.4 (41-130, 55-80.9)	66.1 (49.3-87.1, 63.6-79)	73.8 (40.4-131, 62.3-81.7)
Pre-Dose Vital Signs				
Systolic BP, mmHg, median (range, IQR)	126 (92-166, 109-137)	133 (64-177, 112-147)	119 (96-138, 113-131)	112 (81-175, 103-122)
Diastolic BP, mmHg, median (range, IQR)	67 (51-94, 59-74)	70 (32-114, 59-76)	66 (55-83, 59-73)	61 (51-86, 56-67)
Heart Rate, bpm, median (range, IQR)	79 (48-104, 67-91)	80 (50-120, 73-91)	76 (60-100, 69-96)	90 (59-120, 74-98)
Hospital Unit, n (%)				
Not Critical Care / Stepdown	25 (92.6%)	84 (84%)	6 (100%)	36 (94.7%)
Critical Care / Stepdown	2 (7.4%)	16 (16%)	-	2 (5.3%)
ESA Product, n (%)				
Biosimilar	23 (85.2%)	93 (93%)	5 (83.3%)	34 (89.5%)
Originator	4 (14.8%)	7 (7%)	1 (16.7%)	4 (10.5%)

BP = blood pressure; CKD = chronic kidney disease; eGFR = estimated glomerular filtration rate; HD = hemodialysis; IQR = interquartile range; PD = peritoneal dialysis; RRT = renal replacement therapy

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Table 6. Results for primary outcome

	CKD (n = 27)	RRT (n = 100)	Oncology (n = 6)	Other (n = 38)
Hb Target	9 to 11 g/dL	9 to 11 g/dL	CIA: < 10 g/dL MDS: 10 to 12 g/dL	Blood transfusion refusal or surgery: 12 to 13 g/dL
Hb, g/dL, median (range, IQR)	8.4 (6.7-10.5, 7.8-9)	8.3 (4.4-**11.1**, 7.8-9.1)	7.9 (6.5-9, 6.9-8.1)	8.1 (5.5-**13.8**, 7.4-9.8)
Appropriate, n (%)	27 (100%)	99 (99%)	6 (100%)	37 (97.4%)
Comments	All Hb < 11 g/dL	**1 with Hb >11 g/dL**	All Hb < 10 g/dL	n = 32 with surgery **1 with Hb >13 g/dL**

CIA = chemotherapy-induced anemia;
CKD = chronic kidney disease;
Hb = hemoglobin;
IQR = interquartile range;
MDS = myelodysplastic syndrome;
RRT = renal replacement therapy

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Table 7. Additional information stratified by critical and non-critical care settings

Not Critical Care / Stepdown	CKD (n = 25)	RRT (n = 84)	Oncology (n = 6)	Other (n = 36)
Recent RBC Transfusion (≤ 7 days prior)	10 (40%)	19 (22.6%)*	3 (50%)	11 (30.6%)
Pharmacy I-Vents in Epic				
Clinical Manager	1 (4%): *Hb Monitoring: 1*	-	-	-
Staff Pharmacist	8 (32%): *Hb Monitoring: 3* *Indication Clarification: 2* *Dose Increase: 1* *Frequency Clarification: 1* *Product Selection: 1*	12 (14.3%): *Hb Monitoring: 5* *Product Selection: 3* *Schedule Change: 3* *Dose Clarification: 1*	4 (66.7%): *Hb Monitoring: 2* *Hold Therapy: 1* *Schedule Change: 1*	6 (16.7%): *Hb Monitoring: 2* *Frequency Clarification: 2* *Indication Clarification: 1* *Product Selection: 1*
No Documentation	16 (64%)	72 (85.7%)	2 (33.3%)	30 (83.3%)
Critical Care / Stepdown	**CKD (n = 2)**	**RRT (n = 16)**	**Oncology (n = 0)**	**Other (n = 2)**
Recent RBC Transfusion (≤ 7 days prior)	1 (50%)	10 (62.5%)*	-	1 (50%)
Pharmacy I-Vents in Epic				
Clinical Manager	-	-	-	-
Staff Pharmacist	1 (50%): *Product Selection: 1*	5 (31.2%): *Product Selection: 3* *Frequency Clarification: 1* *Hb Monitoring: 1*	-	1 (50%): *Hb Monitoring: 1*
No Documentation	1 (50%)	11 (68.8%)	-	-

CKD = chronic kidney disease;
Hb = hemoglobin;
RBC = red blood cell;
RRT = renal replacement therapy
*p < 0.05

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Table 8. Lab testing within 90 days prior to ESA dose

	CKD (n = 27)	RRT (n = 100)	Oncology (n = 6)	Other (n = 38)
	n (%)	n (%)	n (%)	n (%)
Erythropoietin	1 (3.7%)	5 (5%)	2 (33.3%)	1 (2.6%)
Anemia Panel				
Iron	23 (85.2%)	78 (78%)	6 (100%)	19 (50%)
Ferritin	23 (85.2%)	76 (76%)	6 (100%)	19 (50%)
TSAT	23 (85.2%)	78 (78%)	6 (100%)	19 (50%)
TIBC	23 (85.2%)	77 (77%)	4 (66.7%)	19 (50%)
Vitamin B12	12 (44.4%)	38 (38%)	6 (100%)	12 (31.6%)
Folate	8 (29.6%)	28 (28%)	4 (66.7%)	7 (18.4%)

CKD = chronic kidney disease;
RRT = renal replacement therapy;
TIBC = total iron binding capacity;
TSAT = transferrin saturation

Table 9. Concomitant medications

	CKD (n = 27)	RRT (n = 100)	Oncology (n = 6)	Other (n = 38)
Iron	8 (30.8%)	4 (4%)	1 (16.7%)	20 (51.3%)
Vitamin B12	5 (19.2%)	29 (29%)	3 (50%)	1 (2.6%)
Folic acid	10 (38.5%)	37 (37%)	3 (50%)	22 (56.4%)
VTE Prophylaxis	18 (69.2%)	73 (73%)	2 (33.3%)	30 (76.9%)

CKD = chronic kidney disease;
RRT = renal replacement therapy;
VTE = venous thromboembolism

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