Anemia in Patients With Inflammatory Bowel Disease

These materials were created in conjunction with Pfizer Inc.

Contents

Anemia in Patients With IBD

Definition of Anemia

- Anemia is diagnosed when the concentration of serum hemoglobin (Hb) falls below established thresholds[1]
  - Hb naturally varies with age, sex, pregnancy, altitude, and smoking
  - The capacity of blood to carry oxygen is compromised when Hb levels are too low
  - This results in weakness, dizziness, fatigue, and shortness of breath

WHO Criteria for Minimum Hb Levels (g/dL) Used to Define Anemia[1,2,a]

Individuals (≥15 years)	Healthy	Mild Anemia	Moderate Anemia	Severe Anemia
Nonpregnant women and girls	≥12.0	11.0-11.9	8.0-10.9	<8.0
Pregnant women	≥11.0	10.0-10.9	7.0-9.9	<7.0
Men	≥13.0	11.0-12.9	8.0-10.9	<8.0

- Anemia is recognized as one of the most common complications of IBD[3]
  - The WHO criteria that define anemia apply to patients with IBD[3]
  - Cause of anemia in IBD is multifactorial, with etiologies that often overlap
    - Iron-deficiency anemia (IDA) is the most common form of anemia in IBD, followed by anemia of chronic disease (ACD)[2]

[a]For individuals living at sea level.

ACD=anemia of chronic disease; Hb=hemoglobin; IBD=inflammatory bowel disease; IDA=iron-deficiency anemia; WHO=World Health Organization.

1. World Health Organization. http://apps.who.int/iris/bitstream/handle/10665/259425/9789241513067-eng.pdf?sequence=1. Accessed August 19, 2021. **2.** Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128. **3.** Dignass AU, et al. *J Crohns Colitis*. 2015;9(3):211-222.

Prevalence of Anemia in Patients With IBD

- Estimates of the prevalence of anemia in patients with IBD vary from 6% to 74%[1,2]
  - A US-based cohort study (N=1821) revealed that the 5-year prevalence was 50% in patients with IBD and higher in those with CD than in those with UC (53% and 45%, respectively, *P*=0.001)[1,a]

    Note: This cohort study may be limited by patient selection bias and the availability of certain medical records.
- IBD patients with anemia may have increased duration of anemia compared with both IBD patients without anemia and the general population[2]

- Despite the high prevalence of anemia, patients with IBD may be underdiagnosed and undertreated[3]
  - A nationwide retrospective cohort study of UC patients with anemia (N=585[b]) in the Veterans Affairs database found that among those with mild anemia (n=200), only 47% (94 of 200) had undergone an evaluation for iron status
    - Among patients with a diagnosis of mild IDA (n=49), only 55% (27 of 49) were treated with oral iron therapy
    - No patients received IV iron treatment regardless of anemia severity

  Note: This study may be limited by the retrospective nature, and the Veterans Affairs population predominately comprised middle- to older-aged White men, which can limit the external validity of the study. Additionally, prescriptions filled outside of the database were not captured, and potential misclassification of IDA status may exist.

- The prevalence of anemia may be elevated in patients with IBD with certain risk factors[1,4,5]
  - Have active disease status
  - Are receiving IBD-specific medication
  - Are hospitalized
  - Have undergone surgery for IBD

[a]Patients were seen between 2009 and 2013 at the IBD Center at the University of Pittsburgh Medical Center. A total of 1077 patients had CD and 744 patients had UC. [b]Patients with newly diagnosed UC between 2001 and 2011 in the Veterans Affairs Pharmacy Benefits Management and Corporate Data Warehouse database were included.
CD=Crohn's disease; IBD=inflammatory bowel disease; IDA=iron-deficiency anemia; UC=ulcerative colitis.
1. Koutroubakis IE, et al. *J Clin Gastroenterol*. 2016;50(8):638-643. **2.** Patel D, et al. *Inflamm Bowel Dis*. 2020;26(6):934-940. **3.** Khan N, et al. *Inflamm Bowel Dis*. 2016;22(12):2894-2901. **4.** Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128. **5.** Filmann N, et al. *Inflamm Bowel Dis*. 2014;20(5):936-945.

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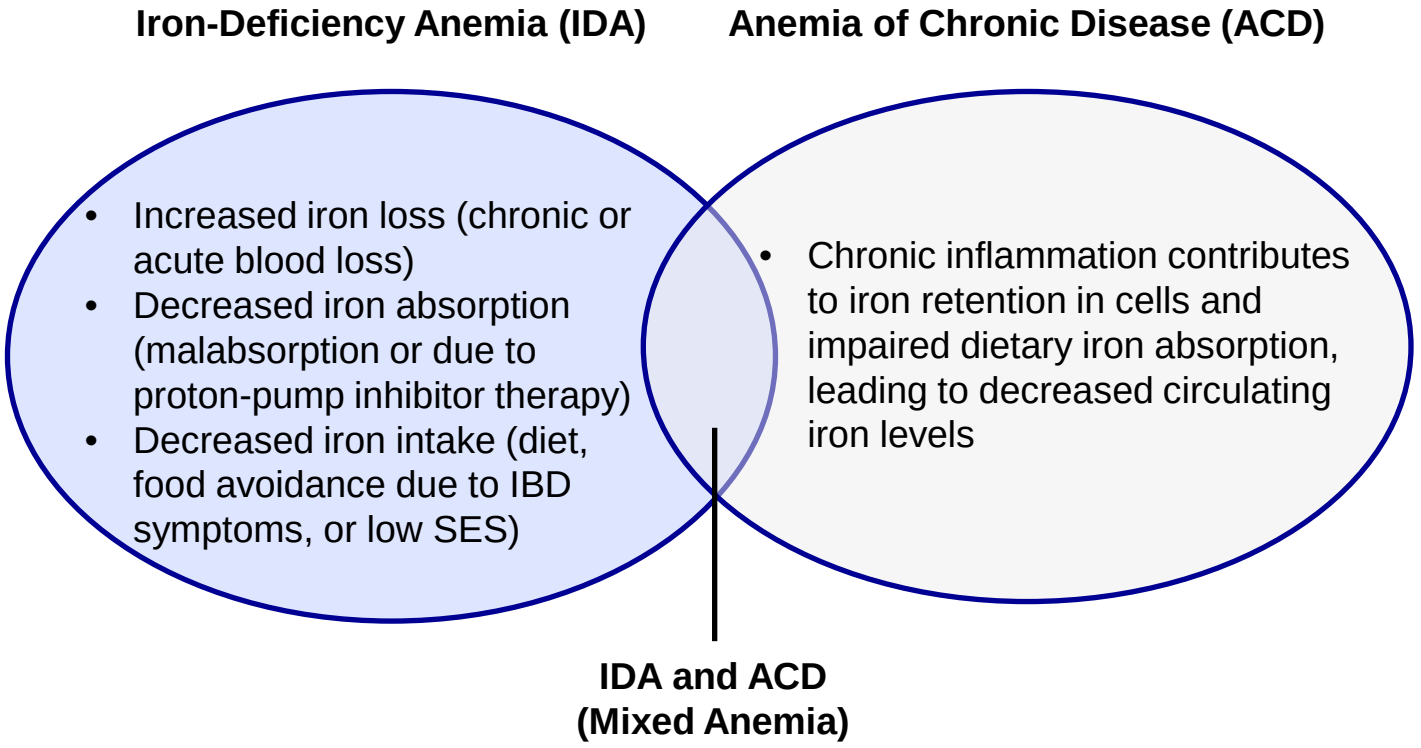
Types of Anemia in Patients With IBD

- The etiology of anemia in patients with IBD is diverse[1]
- IDA is the more common form of anemia in patients with IBD (reported in 36% to 90% of patients with IBD)[1]
  - ACD is more prevalent in patients with advanced disease or those responding poorly to IBD therapy[2]
  - IDA and ACD are not mutually exclusive and can be present in the same patient[1]
- Less common causes of anemia in patients with IBD include vitamin B_{12} deficiency, folate deficiency, autoimmune hemolysis, myelodysplastic syndrome, aplasia, and drug-induced anemia[1]

Common Pathogenesis of the Predominant Forms of Anemia in Patients With IBD[1-4]



ACD=anemia of chronic disease; IBD=inflammatory bowel disease; IDA=iron-deficiency anemia; SES=socioeconomic status.

1. Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128. **2.** Nielsen OH, et al. *Nutrients*. 2018;10(1):E82. **3.** Kaitha S, et al. *World J Gastrointest Pathophysiol*. 2015;6(3):62-72. **4.** Martin J, et al. *Expert Rev Gastroenterol Hepatol*. 2017;11(1):19-32.

Laboratory Characteristics of IDA, ACD, and Mixed Anemia

Laboratory Characteristics of Anemias in Patients With IBD[1]

Laboratory measures	IDA	ACD	IDA and ACD
Serum iron	↓	↓	↓
Hemoglobin	↓	↓	↓
MCV	↓	↓ or normal	↓ or normal
CRP	Normal	↑↑	↑
Serum ferritin	↓	↑	↑ or normal
Transferrin	↑	↓ or normal	↓
Transferrin saturation	↓	↓	↓
sTfR	↑	↓	↑ or normal
sTfR- Ferritin index	High (> 2)	Low (< 1)	High (> 2)
Reticulocyte Hb content (CHr, pg)	< 28	⩾ 28	< 28
Zinc protoporphyrin (µmol/mol heme)	> 40	< 40	> 40
Percentage of hypochromic RBC	> 5	< 5	> 5
Hepcidin	↓	↑	↑

- Serum ferritin is the most common parameter to assess iron storage and can help differentiate between IDA and ACD[2,3]
  - During flares, serum levels of ferritin can be increased by inflammation[2,4]
- Zinc protoporphyrin is unaffected by inflammation and can be an effective indicator of IDA, even in the presence of active disease[5]
- Hepcidin levels may also help identify patients with IDA; however, further studies are needed to validate its use in clinical practice[5,6]

There is no single laboratory parameter that differentiates IDA from ACD[1]

↓=low/decreases; ↑=high/increases; ↑↑=very high; ACD=anemia of chronic disease; CHr=reticulocyte hemoglobin content; CRP=C-reactive protein; Hb=hemoglobin; IBD=inflammatory bowel disease; IDA=iron-deficiency anemia; MCV=mean corpuscular volume; RBC=red blood cell; sTfR=soluble transferrin receptor.

1. Kaitha S, et al. *World J Gastrointest Pathophysiol*. 2015;6(3):62-72. **2.** Niepel D, et al. *Therap Adv Gastroenterol*. 2018;11:1756284818769074. **3.** Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128. **4.** Dignass AU, et al. *J Crohns Colitis*. 2015;9(3):211-222. **5.** Martin J, et al. *Expert Rev Gastroenterol Hepatol*. 2017;11(1):19-32. **6.** Murawska N, et al. *Inflamm Bowel Dis*. 2016;22(5):1198-1208.

Burden of Anemia on Patients With IBD (Quality of Life)

- Anemia is associated with significant impact on the quality of life (QoL) of patients with IBD[1-3]
  - Increased fatigue, reduced physical and cognitive function, and/or increased emotional burden

In a Single-Center Cohort Study (N=50), Treatment of Anemia in Patients With IBD Was Associated With Improved QoL, Independent of Improvement in Disease Activity[2,a]

	Change in Score on QoL Questionnaires[b]	
	Generic QoL Test (SF-36), Mean (SE)	Disease-Specific QoL test (IBDQ), Mean (SE)
Change in QoL score per unit change in Hb (1 g/dL)	3.6 (1.2)*	7.9 (2.8)*
Change in QoL score by disease activity from active to inactive[c]	4.7 (5.3)	6.9 (12.6)

Note: This cohort study may be limited by patient selection bias and a small patient population. Further studies may be required to validate the results of this study.[2]

**P*<0.05. [a]A single-center study of 50 patients with IBD that examined the association between changes in Hb and changes in QoL and cognitive function independent of change in disease activity. [b]The IBDQ is a disease-specific tool for measuring QoL in patients with IBD. It consists of 32 questions, each scored from 1 to 7, giving a range of 32 to 224 (low to high QoL). The SF-36 is a generic validated QoL measure ranging from 0 to 100 (low to high QoL). [c]Disease activity was calculated using a modified Crohn's Disease Activity Index for patients with Crohn's disease (score ≥129 was considered active disease) and the Short Colitis Activity Index for patients with ulcerative colitis (score ≥4 was considered active disease).
Hb=hemoglobin; IBD=inflammatory bowel disease; IBDQ=Inflammatory Bowel Disease Questionnaire; QoL=quality of life; SF-26, 36-Item Short Form Survey.

1. Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128. **2.** Wells CW, et al. *Inflamm Bowel Dis*. 2006;12(2):123-130. **3.** Avni T, et al. *PLoS One*. 2013;8(12):e75540.

Burden of Anemia on Patients With IBD (Economic)

A Retrospective US Cohort Study of Adult Patients With IBD (N=1763[a]) Investigated the Impact of Anemia on Healthcare Utilization and Costs

- Compared with IBD patients without anemia, those with anemia and IBD had
  - More hospitalizations, longer hospital stays, and more visits to ER, gastroenterology clinic, and PCP
  - A 97.8% increase in total direct costs
- Increased severity of anemia correlated with elevated healthcare utilization and costs, independent of IBD disease activity as measured by CRP and/or fecal calprotectin

Mean Direct Costs for IBD Patients With and Without Anemia

Cost category	Anemic (mean cost ($), SD)	Non-anemic (mean cost ($), SD)	*P*
Clinic cost	$607.24 (831.24)	$318.42 (329.55)	<0.0001
ER cost	$446.95 (1223.68)	$96.88 (330.72)	<0.0001
GI cost	$458.64 (609. 43)	$307.01(424.61)	0.0047
Laboratory cost	$1294.95 (1386.71)	$604.72 (801.60)	<0.0001
Pharmacy cost	$10,201.89 (24,358.04)	$4626.8 (18,280.42)	<0.0001
Admission cost	$1938.56 (4402.01)	$230.91 (979.26)	<0.0001
Other cost	$2452.53 (7550.75)	$1249.27 (6218.26)	<0.0001
Total cost	$19,627.18 (31,346.16)	$7975.74 (21,684.87)	<0.0001

Note: This cohort study may be limited by its retrospective nature and inherent limitations of the EMR. Additionally, visits and costs outside of the healthcare system as well as indirect costs were not accounted for in this analysis. Finally, the absence of iron status from many patients also limited the investigation on possible differences regarding anemia etiology.

[a]EMR data from a single, tertiary referral center in the United States between 2014 and 2018 were used in the analysis. Among patients with IBD, 966 had CD, 799 had UC, and 18 had IBDU. Of the 1763 patients, 951 had a diagnosis of anemia.

CD=Crohn's disease; CRP=c-reactive protein; EMR=electronic medical record; ER=emergency room; GI=gastroenterologist; IBD=inflammatory bowel disease; IBDU=inflammatory bowel disease undetermined; PCP=primary care physician; UC=ulcerative colitis.

Blaney H, et al. *Dig Dis Sci*. 2020;66(8):2555-2563.

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Managing Anemia in Patients With IBD

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Management of Anemia: Recommendations for Patients With IBD

Adapted From the Crohn's & Colitis Foundation's Anemia Care Pathway

Screening

- Driven by patient symptoms and/or provider recognition of laboratory abnormalities
- Assess Hb and iron (ferritin) levels

Evaluation

- Further laboratory evaluation may be required
- Patients should be classified based on iron stores (assess ferritin and transferrin levels)

Intervention

- Based on the type and severity of anemia, IBD disease activity, and other factors, determine the appropriate type of iron therapy that may be needed
- Referral to a hematologist may be required

Follow-up

- Assess response (Hb levels) 4 weeks after treatment initiation[a]
- If anemia has not been resolved, consider escalation of therapy or hematology referral, as needed

(For Anemia Care Pathway Flowchart)

[a]If the patient responds to therapy, repeat Hb assessment at 8 weeks. If persistent fatigue has resolved, Hb levels and symptoms of anemia can be monitored thereafter at clinical appointments.

Hb=hemoglobin; IBD=inflammatory bowel disease.

Crohn's & Colitis Foundation. https://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/anemiafactsheet.pdf. Accessed August 19, 2021.

Screening and Evaluation of Anemia in Patients With IBD

Anemia Screening Recommendations

- Screening for anemia should follow WHO recommendation for Hb thresholds[1]
  - If Hb levels are below normal, further laboratory workup should be initiated
  - At minimum, check for red blood cell indices, reticulocyte count, differential blood cell count, serum ferritin, transferrin saturation, and CRP concentration
- Recommended screening frequency in patients with IBD[1,a]:
  - Patients in remission or mild disease: screen every 6 to 12 months
  - Patients with active disease: screen every 3 months
- Anemia screening should also occur in all patients with IBD to assess symptoms of fatigue and bleeding, as well as Hb and ferritin levels[2,b]

Recognition of Anemia in Patients With IBD Remains Suboptimal[2,3]

- Potential barriers of recognizing anemia in patients with IBD[2]:
  - Lack of active screening for anemia
  - Uncertainty in defining iron deficiency among patients with IBD
  - Lack of awareness of non-anemic iron deficiency
  - Perception that management of anemia is less important than management of IBD

[a]Guidelines put forth by the European Crohn's and Colitis Organisation (2015). [b]As recommended by the Crohn's & Colitis Foundation (2017).
CRP=C-reactive protein; Hb=hemoglobin; IBD=inflammatory bowel disease; WHO=World Health Organization.
1. Dignass AU, et al. *J Crohns Colitis*. 2015;9(3):211-222. **2.** Hou JK, et al. *Inflamm Bowel Dis*. 2017;23(1):35-43. **3.** Akhuemonkhan E, et al. *BMJ Open Gastroenterol*. 2017;4(1):e000155.

Treatment of IDA in Patients With IBD

- Imbalances in iron homeostasis, which underlie IDA, are primarily treated with iron replacement therapy[1,2]
- Oral and IV formulations are available for iron supplementation[1,2]
  - Oral iron can be used for prophylaxis (30 mg/d) and treatment (50-100 mg/d) of IDA[3,4]
  - Oral iron is sometimes associated with gastrointestinal side effects (eg, abdominal pain, nausea, flatulence, diarrhea), slower response, and nonadherence[1,3,5,6]
  - IV iron may therefore be considered the first-line therapy for patients with moderate to severe anemia and active IBD, whereas oral iron may be more appropriate for patients with mild anemia and inactive IBD[1,4-6,a,b]

[a]Guidelines put forth by the European Crohn's and Colitis Organisation (2015). [b]As recommended by the Crohn's & Colitis Foundation (2017).
IBD=inflammatory bowel disease; IDA=iron-deficiency anemia; IV=intravenous.
1. Dignass AU, et al. *J Crohns Colitis*. 2015;9(3):211-222. **2.** Nielsen OH, et al. *Nutrients*. 2018;10(1):E82. **3.** Murawska N, et al. *Inflamm Bowel Dis*. 2016;22(5):1198-1208.
4. Hou JK, et al. *Inflamm Bowel Dis*. 2017;23(1):35-43. **5.** Aksan A, et al. *Aliment Pharmacol Ther*. 2017;45(10):1303-1318. **6.** Lugg S, et al. *J Crohns Colitis*. 2014;8(8):876-880.

Iron Replacement Formulations to Treat Anemia in Patients With IBD: Pros and Cons

Pros and Cons of Iron Replacement Formulations in Patients With IBD[1-3]

	Advantages	Disadvantages
Oral iron	• Relatively low cost • Convenient route of administration • Availability over the counter	• Compliance issues associated with gastrointestinal adverse events • Low intestinal absorption
IV iron	• Benefit in patients who do not tolerate oral iron • Effectiveness in supplying iron for erythropoiesis • Rapid increase in iron stores, serum ferritin, and Hb • Effectiveness when inflammation is present • Improved safety profile of newer IV formulations, including reduced occurrence of anaphylactic reaction	• Risk of local and systemic adverse events (anaphylactic reactions, hypotension, nausea, cramps) • Requirement for IV access • Higher cost • Potential for iron overload (and transient increase in oxidative stress), as well as hypophosphatemia

Hb=hemoglobin; IBD=inflammatory bowel disease; IV=intravenous.

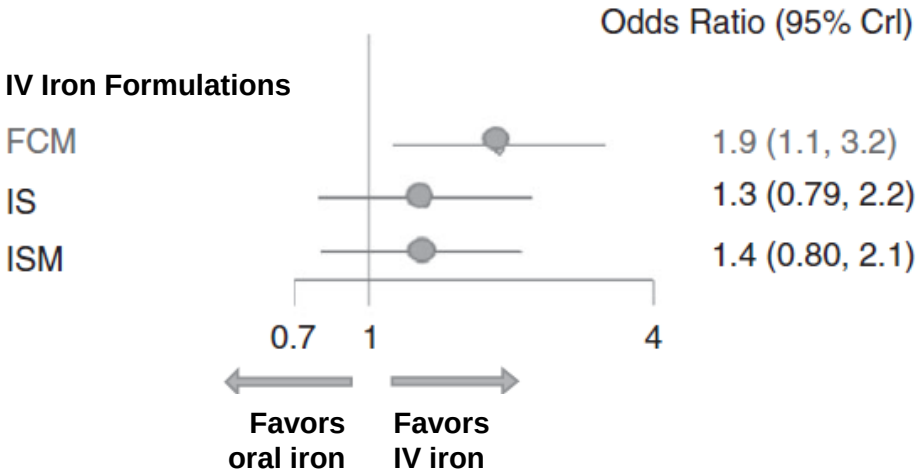
1. Nielsen OH, et al. *Nutrients*. 2018;10(1):E82. **2.** Murawska N, et al. *Inflamm Bowel Dis*. 2016;22(5):1198-1208. **3.** Bou-Fakhredin R, et al. *Expert Rev Hematol*. 2017;10(9):801-808.

Effectiveness of Oral and IV Iron in Patients With IBD and Anemia

- Treatment with IV iron has been associated with better outcomes such as higher rate of Hb improvement, better rates of medication adherence, and less frequent serious AEs than oral iron therapy[1]
- IV iron treatment provided by a gastroenterologist has been reported to be effective and safe, and can improve the quality of life for IBD patients with anemia[2]

A Network Meta-analysis of 5 RCTs in Patients With IBD (N=1143) Investigated the Efficacy of IV Iron Therapy[3,a]

Efficacy Compared With Oral Iron



- IV iron formulations were associated with better efficacy outcomes than oral formulations
- Only FCM was associated with significantly higher efficacy compared with oral formulations

Note: This systematic reviews with meta-analysis integrated the results of multiple studies and may be limited by clinical and/or statistical heterogeneity of studies included, treatment of covariates that may impact the outcome of the study, and selection bias.

[a]Efficacy was based on Hb normalization and/or increase by ≥2 g/dL.

AE=adverse event; CrI, credible interval; FCM=ferumoxytol and ferric carboxymaltose; Hb=hemoglobin; IBD=inflammatory bowel disease; IS=iron sucrose/saccharate; ISM=iron isomaltoside; IV=intravenous; RCT=randomized controlled trial.

1. Avni T, et al. *PLoS One*. 2013;8(12):e75540. **2.** Coe CL, et al. *Crohns Colitis 360*. 2020;2(3):otaa051. **3.** Aksan A, et al. *Aliment Pharmacol Ther*. 2017;45(10):1303-1318.

Treatment of ACD in Patients With IBD

- Primary treatment approach for ACD is to address the underlying pathology contributing to anemia[1,2]
  - For patients with IBD, an important step to treat ACD is to induce complete remission of IBD[1,3,a]
  - For patients with uncontrolled IBD or patients with additional known pathologies or deficiencies (eg, vitamin deficiencies) that are contributing to anemia, erythropoiesis-stimulating agents and/or vitamin supplementation may be considered[1,2]
  - Treatment of anemia should not be delayed for treatment of active IBD; it can occur concurrently with IBD therapy[4,b]

- Red blood cell transfusions may be indicated in cases of severe anemia (ie, Hb <7-8 g/dL), in which rapid correction of Hb levels is needed[2]
  - Patients with rapidly developing anemia in association with acute gastrointestinal bleeding
  - Patients who suffer from comorbidities such as coronary heart disease or chronic pulmonary disease
- Use of blood transfusions must be considered carefully[2]
  - Liberal use of transfusions has been associated with higher mortality rates, increased risk of nosocomial infections, higher frequency of surgical-site infections, transfusion-related anaphylactic reactions, and a small but residual risk of transmitting infectious disease

[a]Guidelines put forth by the European Crohn's and Colitis Organisation (2015). [b]As recommended by the Crohn's & Colitis Foundation (2017).
ACD=anemia of chronic disease; Hb=hemoglobin; IBD=inflammatory bowel disease.
1. Dignass AU, et al. *J Crohns Colitis*. 2015;9(3):211-222. **2.** Nielsen OH, et al. *Nutrients*. 2018;10(1):E82. **3.** Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128.
4. Hou JK, et al. *Inflamm Bowel Dis*. 2017;23(1):35-43.

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Summary

- **Anemia is recognized as one of the most common complications of inflammatory bowel disease (IBD)**
  - The prevalence of anemia in patients with IBD ranges from 6% to 74%, with higher prevalence among patients who have active disease, who are receiving IBD-specific medication, who are hospitalized, or who have undergone surgery for IBD
  - Anemia is more common in patients with Crohn's disease than in those with ulcerative colitis
  - Despite the high prevalence of anemia, patients with IBD may be underdiagnosed and undertreated
- **Anemia has a diverse etiology in patients with IBD but is most often a result of iron deficiency (IDA) or a consequence of chronic inflammation (ACD)**
  - Mechanisms for anemia in patients with IBD may include decreased iron intake, increased iron loss, decreased iron absorption, and/or increased cell retention of iron
- **Anemia is associated with considerable impact on the quality of life of patients with IBD and also adds a sizable healthcare burden**
- **Treatment of anemia in patients with IBD depends on the etiology of the anemia**
  - IDA: Iron replacement therapy is recommended; IV iron may be more appropriate for patients with moderate to severe anemia and active IBD, whereas oral iron may be more appropriate for patients with mild anemia and inactive IBD
  - ACD: Primary approach is to address the underlying pathology contributing to anemia; red blood cell transfusions may be indicated in cases of severe anemia, in which rapid correction of hemoglobin levels is needed

ACD=anemia of chronic disease; IBD=inflammatory bowel disease; IDA=iron-deficiency anemia; IV=intravenous.

Resources and References

Available Resources

- American Society of Hematology
- Crohn's & Colitis Foundation
  - Anemia Care Pathway
- European Crohn's and Colitis Foundation
  - Anaemia Consensus
- World Health Organization
  - Nutritional anaemias: tools for effective prevention and control

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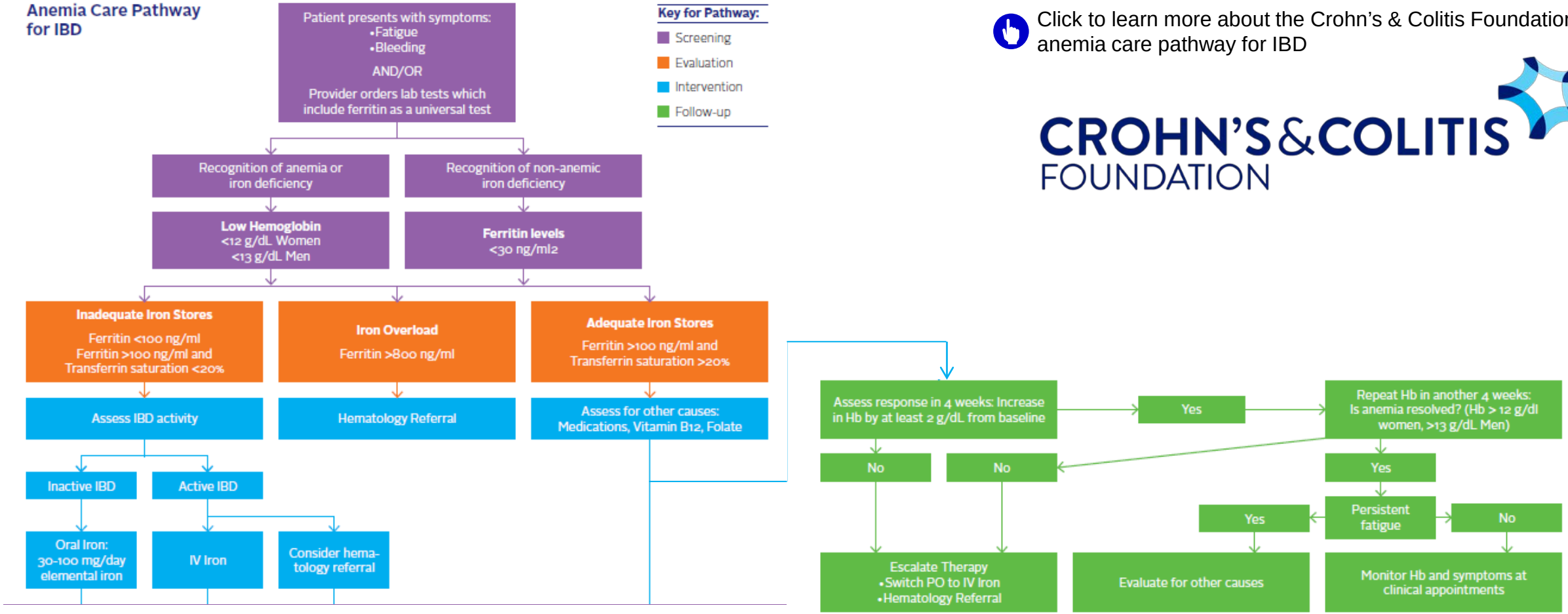
Backup

Crohn's & Colitis Foundation's Anemia Care Pathway for Patients With IBD



Click to learn more about the Crohn's & Colitis Foundation's anemia care pathway for IBD

Hb=hemoglobin; IBD=inflammatory bowel disease; IV=intravenous; PO=per os.

Crohn's & Colitis Foundation. https://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/anemiafactsheet.pdf. Accessed August 19, 2021.

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