Live. Learn. Hope.

CRITICAL THINKING SKILLS: LABS, MEDICATION PROTOCOLS, & NURSING IMPLICATIONS

An Independent Study Module For Advanced Nephrology Nursing

NORTHWEST
Kidney Centers

Live. Learn. Hope.

Anemia Management – ESA - Mircera

Clinical Education
4/2021

NORTHWEST Kidney Centers

Disclaimer

- The Independent Study Training Plans were developed in 2021 and will be available for Continuing Education Credits until 2023.

- During this period, policies, protocols, procedures, and supplies may change. Therefore, **ALWAYS** refer to K-NET and Policy Manager for the most current information.

- Remember that these Independent Study modules are designed to stimulate critical thinking skills and introduce/review the different workflow processes

Learning Objectives

At the end of the presentation, the nurse will be able to:

1. Understand the roles of kidneys in preventing anemia
2. Enumerate causes of anemia in ESRD patients
3. Comprehend the functions of ESA in treatment of anemia
4. Have a basic understanding of the ESA protocol & tools available

Kidney & Anemia - Review

- The kidneys produce 90% of erythropoietin
- Erythropoietin stimulates bone marrow to produce RBCs
- Kidney disease affects / reduces erythropoietin production that leads to anemia
- Patients with kidney failure will need erythropoietin stimulating agents (ESAs) to help produce RBCs

Complications of Anemia in CKD

- **Definite**: Fatigue, shortness of breath, need for blood transfusions
- **Probable**: Reduced quality of life.
- **Possible**: Increased cardiac events (heart attacks, thickening of the heart muscle)

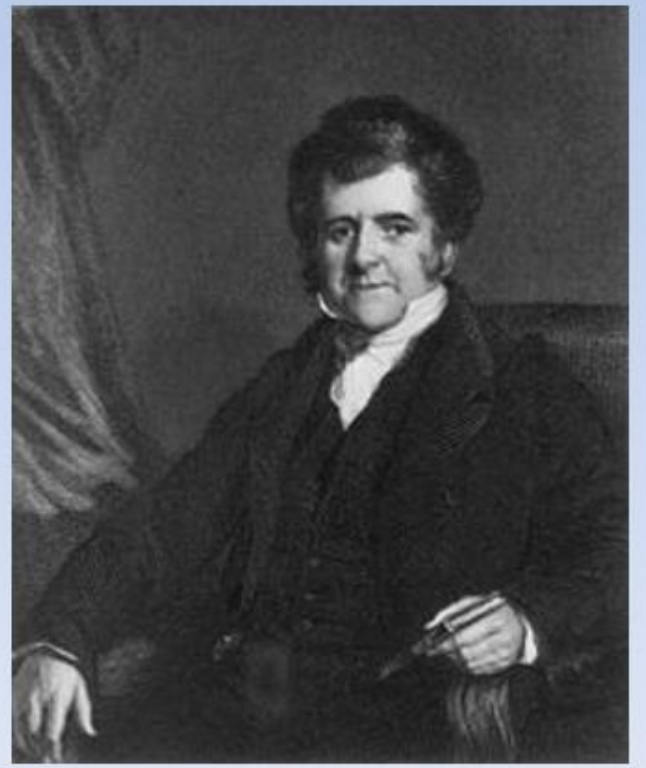
Anemia in CKD has been associated with increased risk of morbidity & mortality.

Other Signs & Symptoms

- Headache
- Dizziness
- Feeling cold
- Brittle nails
- Pale skin
- Forgetfulness

Anemia Background Info

- Anemia was first linked to kidney disease over 170 years ago by Richard Bright.
  - English physician
  - "Father of nephrology"
- Nearly all patients who start dialysis today are anemic.



Richard Bright, 1789 - 1858

Seminal Study (1989)

- Eschbach et al: Recombinant human erythropoietin in anemic patients with end stage renal disease. Ann Intern Med. 1989 Dec 15;111(12):992-1000.

- Phase 3 study that paved the way to Epoetin's initial FDA approval.

Seminal Study (1989)

- n=333 hemodialysis patients with hematocrit < 30%, given Epogen.
- Mean hematocrit increased from 22.3% -> 35%.

- Transfusion decreased from 1030 in previous 6 months to virtually none (!).

Epoetin Alpha

- Single greatest drug expenditure paid by the U.S. Medicare system
  - In 2010, the program paid $2 billion for the drug

Causes of Anemia in CKD / HD

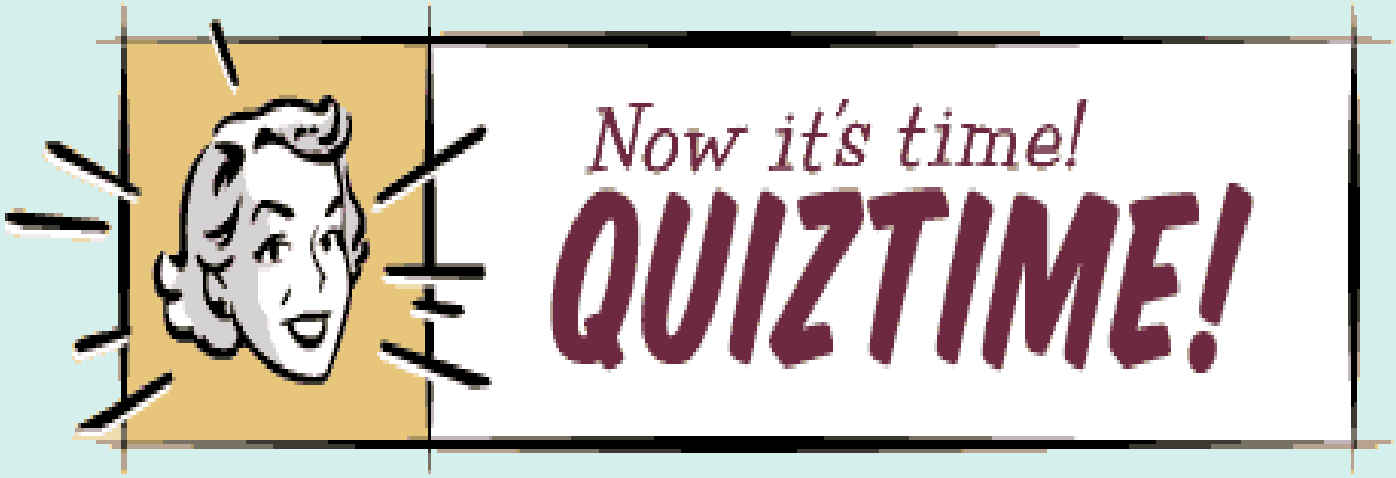
- Erythropoietin deficiency – kidney failure
- Blood loss – from bleeding, clotting of extracorporeal circuit, & other source
- Nutritional deficiency – iron, folate, & Vit B12
- Inflammatory block – d/t uremia & dialysis

Currently Available ESAs

ESA = **E**rythropoetin-**S**timulating **A**gents

- Recombinant human erythropoietin (rHuEPO)
  - Epoetin alpha (Procrit, Epogen, Retacrit)
  - Epoetin beta (Epogin, NeoRecormon, Recormon)
  - Epoetin theta (Biopoin, Eporatio)
- Longer-acting ESA
  - Darbepoetin alpha (Aranesp)
  - Methoxy polyethylene glycol-epoetin beta (Mircera)
- Biosimilars
  - HX575 (Sandoz)
  - SB309 (Hospira)

Were You Paying Attention?



Before We Discuss the Protocol…

Question # 1

What is the correlation between kidney failure and anemia?

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Answer:

One of the supporting functions of the kidney is to produce the hormone erythropoietin (Epo).

Epo stimulates bone marrow to produce RBCs.

When kidneys fail, Epo release diminishes resulting in decline in RBC production which leads to anemia.

Question # 2

List at least 5 complications and signs & symptoms associated with anemia on CKD patients.

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Answers:

- **Definite**: Fatigue, shortness of breath, need for blood transfusions
- **Probable**: Reduced quality of life.
- **Possible**: Increased cardiac events (heart attacks, thickening of the heart muscle)
- Other signs & symptoms: headache, dizziness, feeling cold, brittle nails, pale skin, & forgetfulness

Question # 3

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Answer:

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Question # 4

What are the causes of anemia in CKD, specifically on HD patients?

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Answers:

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- Inflammatory block – d/t uremia & dialysis

Question # 5

Which ESA do we currently use at NKC to treat anemia in CKD patients & which ICD10 code do we use for the order?

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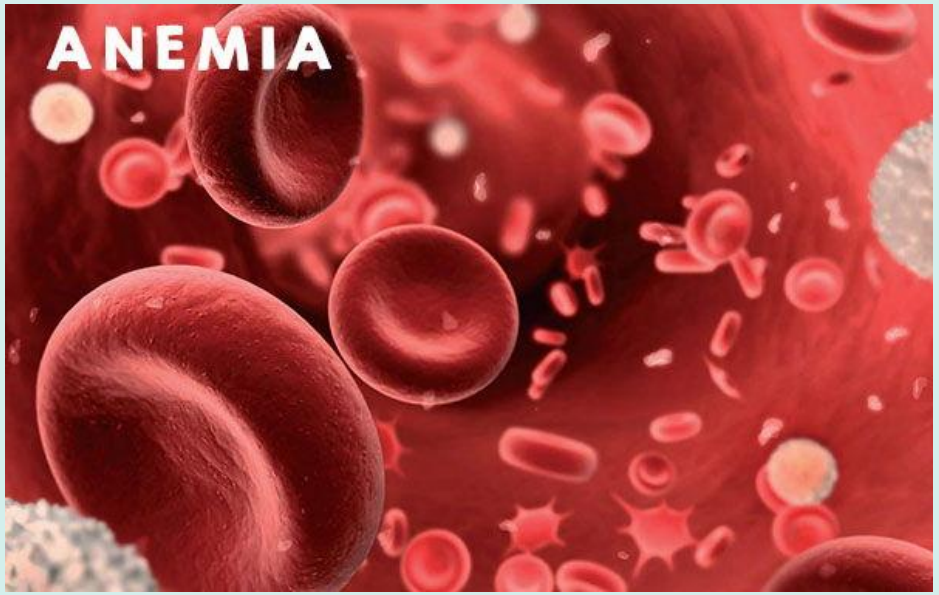
Answer:

Methoxy polyethylene glycol-epoetin beta (Mircera®)

ICD10 code = D63.1 Anemia in chronic kidney disease

Now the Protocol



Mircera® Protocol

Methoxy polyethylene glycol-epoetin beta (Mircera®)

ICD 10 code D63.1 Anemia in chronic kidney disease

Purpose: To provide optimal management of ESRD related anemia in dialysis patients

Hemoglobin Target Goal: **10.0-11.0 g/dL**

CBC drawn monthly – additional Hgb per MD order

Mircera ® Dosing Table

Methoxy polyethylene glycol-epoetin beta Dosing:

Doses are based on estimated dry weight and rounded to the following steps:

Step	Dose
1	30 mcg every *four* weeks
2	50 mcg every *four* weeks
3	30 mcg every two weeks
4	50 mcg every two weeks
5	60 mcg every two weeks (30 mcg + 30 mcg)
6	75 mcg every two weeks
7	100 mcg every two weeks
8	150 mcg every two weeks
9	200 mcg every two weeks

Table 1

1. Methoxy polyethylene glycol-epoetin (Mircera®) will be increased and decreased in 1-step or 2-step increments, based on scale above.
2. Mircera® will be administered IV to in-center hemodialysis patients, and SQ to home dialysis patients.
3. Mircera® ceiling is 200 mcg every two weeks (or 3.0 mcg/kg/2 weeks, whichever is lower). Orders above 200mcg every two weeks require facility medical director or CMO approval.

Initiating Mircera for New Patients

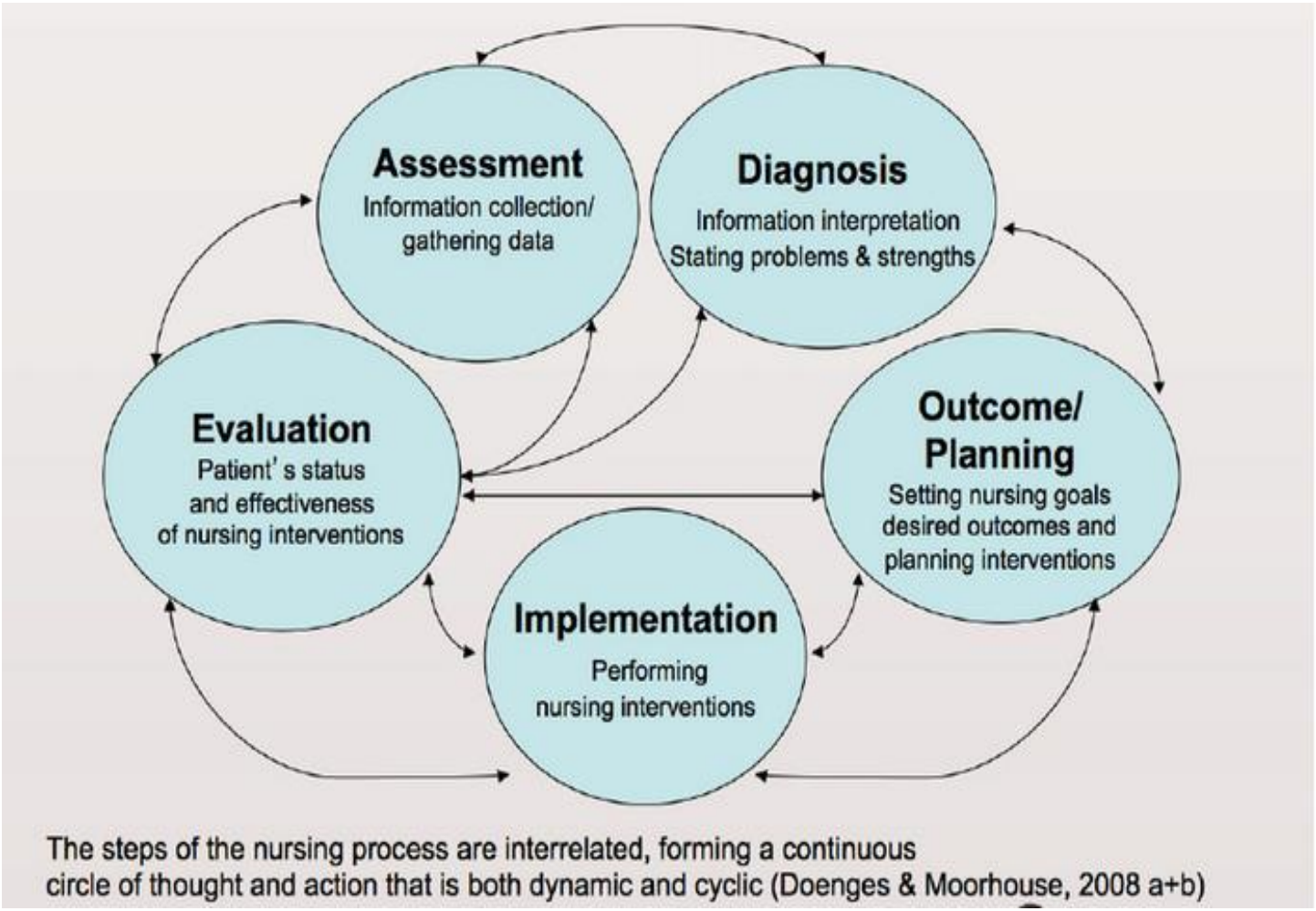
- For new patients or established patients who have not received an ESA within the last 3 months, initiate as follows:

- 1. Iron repletion per iron standing orders
- 2. **AND**
  a. If Hgb < 10 g/dL, then start Mircera® at 0.6 mcg/kg/2 weeks, and round down to closest step per Table 1 but no less than 30 mcg every 2 weeks (Step 3).

  b. If Hgb 10.0-10.4 g/dL, then start Mircera® at 30 mcg every 2 weeks (Step 3).

  c. If Hgb >= 10.5 g/dL, then do not start Mircera® until patient meets criteria.

Remember The Nursing Process!



The steps of the nursing process are interrelated, forming a continuous circle of thought and action that is both dynamic and cyclic (Doenges & Moorhouse, 2008 a+b)

So, Let's Practice That Protocol

Case Study:

Mr. A started this week and the initial Hgb was 9.8 gm/dL
His TW is 72Kg and he has not received any ESA in the past 3 months.

What will be Mr. A's initial Mircera dose?

Let's Work It Out!

Look at Hgb first: result = 9.8gm/dL Where does this result fit in the protocol?

Answer: If Hgb < 10 g/dL, then start Mircera® at 0.6 mcg/kg/2 weeks, and round down to closest step per Table 1 but no less than 30 mcg every 2 weeks (Step 3).

Dose calculation: 0.6mcg per Kg = 0.6mcg x 72 Kg= 43.2mcg **BUT** we need to "round down" to the closest step which is 30mcg Q four weeks (Step 3)

Note: New starts are not placed on "every four weeks" interval

Step	Dose
1	30 mcg every *four* weeks
2	50 mcg every *four* weeks
3	30 mcg every two weeks
4	50 mcg every two weeks
5	60 mcg every two weeks (30 mcg + 30 mcg)
6	75 mcg every two weeks
7	100 mcg every two weeks
8	150 mcg every two weeks
9	200 mcg every two weeks

Remember About Initial Dose

Since our new pt.'s initial Hgb was < 10 g/dL, we had to do some calculation using the 06.mcg/Kg/2 weeks formula

If our new pt.'s Hgb result was between 10.0-10.4 g/dL, the pt. would receive 30 mcg Q 2 weeks

If the Hgb result was equal to or greater than 10.5 g/dL, we will not start Mircera® until result is below 10.5 g/dL

Result the Following Month

A month later, our pt.’s Hgb went up to 10.1 g/dL.

What shall we do with the Mircera® dose?

Dose Adjustments After Initial Dose

What will determine if there's going to be a dose change?

Think: Did Hgb increase or decrease from last draw and by how much?

Magic number: 0.5g/dL change

1. Hgb decreased by greater than or equal to 0.5 g/dL since last dose change
2. Hgb increased/decreased by less than 0.5 g/dL since last dose change
3. Hgb increased greater than or equal to 0.5 g/dL since last dose change
4. Greater than or equal to 12 g/dL = **HOLD**

Dose Adjustments After Initial Dose

1. Assess the info we have:

Lab Test	Current Results	Previous Results
Hgb	10.1	9.8

ESA Management	
Mircera® Dose	30 mcg Q 2weeks

2. Evaluate/interpret & apply the protocol

First: Did the pt. meet the Hgb "Target Goal?"

= Yes, goal is 10.0-11.0 g/dL

Then: Current Hgb increased by 0.3 g/dL from previous

Hgb increased/decreased by less than 0.5 g/dL since last dose change	
Hgb (g/dL)	**Step Dose Change**
Less than 9.5	2 step dose increase
9.5-9.9	1 step dose increase
10.0-10.4	1 step dose increase, if Hgb decreased; do not change if Hgb increased or stayed the same
10.5-11.4	No change
11.5-11.9	1 step dose decrease; if patient is on Step 1, do not HOLD

The dose will be:

Step	Dose
1	30 mcg every *four* weeks

ESA Dose Adjustments

Significant change:

If Hgb is increased or decreased at least 1.0 g/dL since the last Hgb level; recheck Hgb within next 2 dialysis treatments for in-center HD and at next redraw for home patients.

- Use the Nursing Process
  - Assess for what happened?
  - Check root cause – was lab properly drawn?
  - Assess the patient
  - Look at trends

Significant Change - increase

If Hgb **increased** by or more than 1.0 g/dl since the last Hgb level

What are the nursing implications?

First: assess the validity of the result by looking at trends. Is there an error on lab draw?

Second: assess pt. – recent hospitalization? Recent blood transfusion? Taking any meds that could affect results (Iron, Vitamins, etc.)?

Third: Follow protocol and apply dose adjustment as indicated

Fourth: Monitor next result – especially if ESA was held – could have drastic effect the other direction

Significant Change - decrease

If Hgb **decreased** by or more than 1.0 g/dl since the last Hgb level

What are the nursing implications?

First: assess the validity of the result by looking at trends. Is there an error on lab draw?

Second: assess pt. for blood loss, GI bleed, prolonged bleeding from access sites, excessive clotting in dialyzer &/or VDB, any meds affecting the result, recent hospitalization?

Third: Follow protocol and apply dose adjustment as indicated & notify MD

Fourth: Monitor next result closely

Hgb Below Target Goal

Per protocol, DO NOT CHANGE DOSE of Mircera® more frequently than every 4 weeks EXCEPT:

1. If Hgb falls from above 10 g/dL to less than 10 g/dL, increase dose after 2 weeks.

2. If Hgb is already less than 10 g/dL and drops greater than 0.5 g/dL, increase dose after 2 weeks.

Hgb Above Target Goal

If Hgb is greater than or equal to 12 g/dL:

1. HOLD Mircera®
2. Check Hgb Q week – incenter patients
3. Resume Mircera® with 1-Step decrease as soon as Hgb <11.8 g/dL AND last dose was administered 2 weeks ago or more
4. If Hgb remains >= 12 g/dL for more than 2 months, return to regular Hgb testing policy (currently monthly).

What Tools Do Nurses Have?

How can you quickly review & act on Hgb results?

Go to "Ascend LabCheck" > Click on "Reports" > "Custom"

You can create your own custom report(s) or select from the list. Here's a sample:

Auburn Kidney Center
1501 West Valley Highway N, Auburn, WA 98001

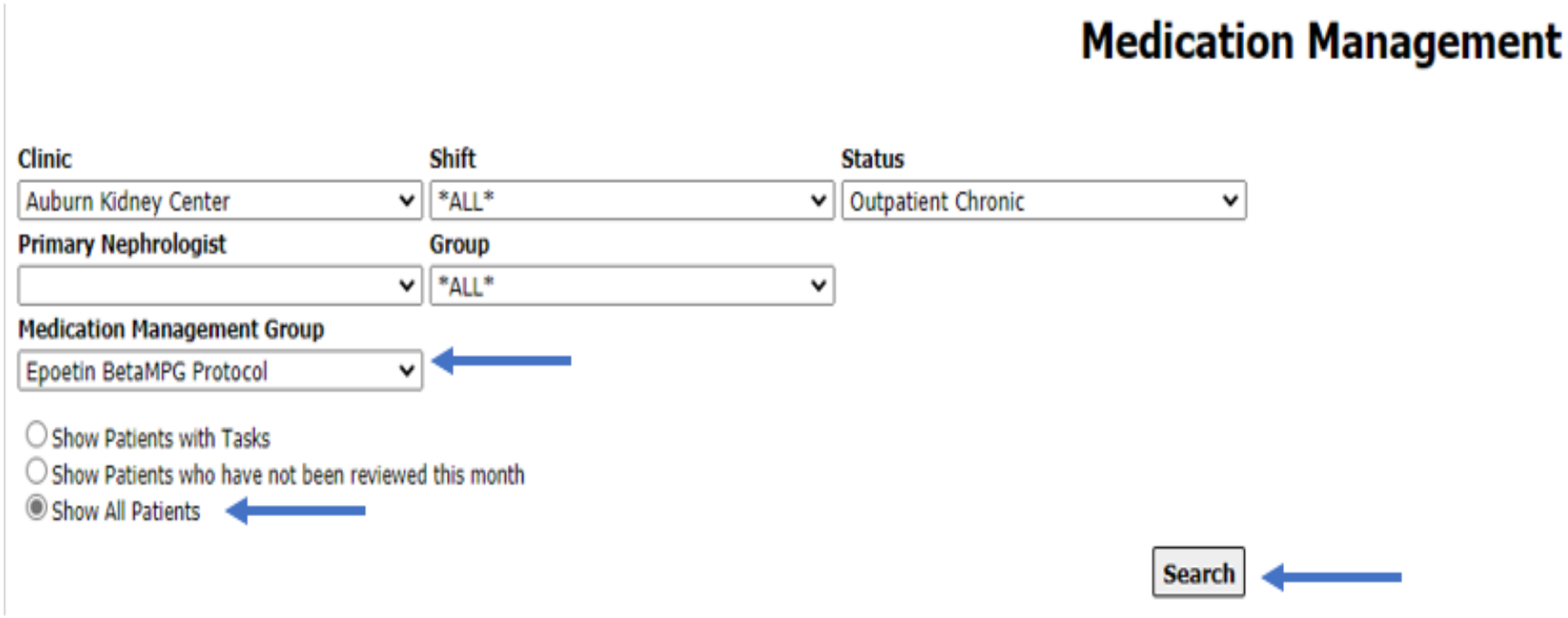
Anemia Management

02/01/2021 to 02/18/2021

Collected	Patient Name	Nephrologist	<=6 HGB	>=6.1 <=9.9 HGB	>=10 <=11 HGB	>=12 HGB	HCT	
02/03/2021				9.5			27.8	
02/15/2021				9.1			27.0	
02/02/2021						12.0	39.9	
02/11/2021						12.4		
02/03/2021						13.7	41.3	
02/03/2021					10.4		32.8	
02/02/2021					10.3		35.6	

What Tools Do Nurses Have?

In Clarity, go to "Patient" > "Medications Management" > "Medication Management" > select "Epoetin BetaMPG Protocol" select "Show All Patients" then click "Search"



What Tools Do Nurses Have?

The "Medication Management Protocol" program in Clarity will show the five most recent Hgb results & provide the dose adjustment calculations & recommendations based on the ESA protocol. Tip: Always double check the dose!

Item	Value
Dialysis Access	AV Fistula - Forearm Left Available Placed on: 06/09/2017 by: HAYDU, JOSEPH A
Dry Weight	99.00 Kg (Outpatient Hemodialysis)
Average HGB (last 3 months)	9.8
HGB	**02/02/2021** 9.1 · **01/05/2021** 10.0 · **12/03/2020** 10.2 · **11/03/2020** 10.4 · **10/06/2020** 10.5
Hematopoietics	**epoetin beta-methoxy polyethylene glycol** 100 mcg intravenously (100 mcg/0.3 mL solution) each Tue every 2 weeks (Next Dose: 03/02/2021) **02/06/2021** 50 mcg intravenously (50 mcg/0.3 mL solution) each Tue every 2 weeks (Next Dose: 02/16/2021) **01/13/2021 - 02/05/2021** 30 mcg intravenously (30 mcg/0.3 mL solution) each Tue every 2 weeks (Next Dose: 01/19/2021) **12/07/2020 - 01/12/2021** 50 mcg intravenously (50 mcg/0.3 mL solution) each Sun every 4 weeks (Next Dose: 12/27/2020) **11/07/2020 - 12/06/2020** 30 mcg intravenously (30 mcg/0.3 mL solution) each Sun every 4 weeks (Next Dose: 11/29/2020) **10/30/2020 - 11/06/2020** 30 mcg intravenously (30 mcg/0.3 mL solution) each Thr every 4 weeks (Next Dose: 10/29/2020) **07/15/2020 - 10/30/2020**

In Closing

Using the "Nursing Process" when reviewing lab results – look at the overall picture. It is not just about the results (numbers)!

Always start with complete assessment:

- Collect additional data
- Look at trends
- Assess the pt., ask questions
- Review comorbid conditions
- Look for s/s associated with abnormal results

Collaborate with the members of the IDT – especially with the patients. The patients are the main driver for these results.

References

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Questions?