

Screen-by-Screen Storyboards

ESA HUB PROGRAM

AMI CRITICAL THINKING VIDEO

AMGEN

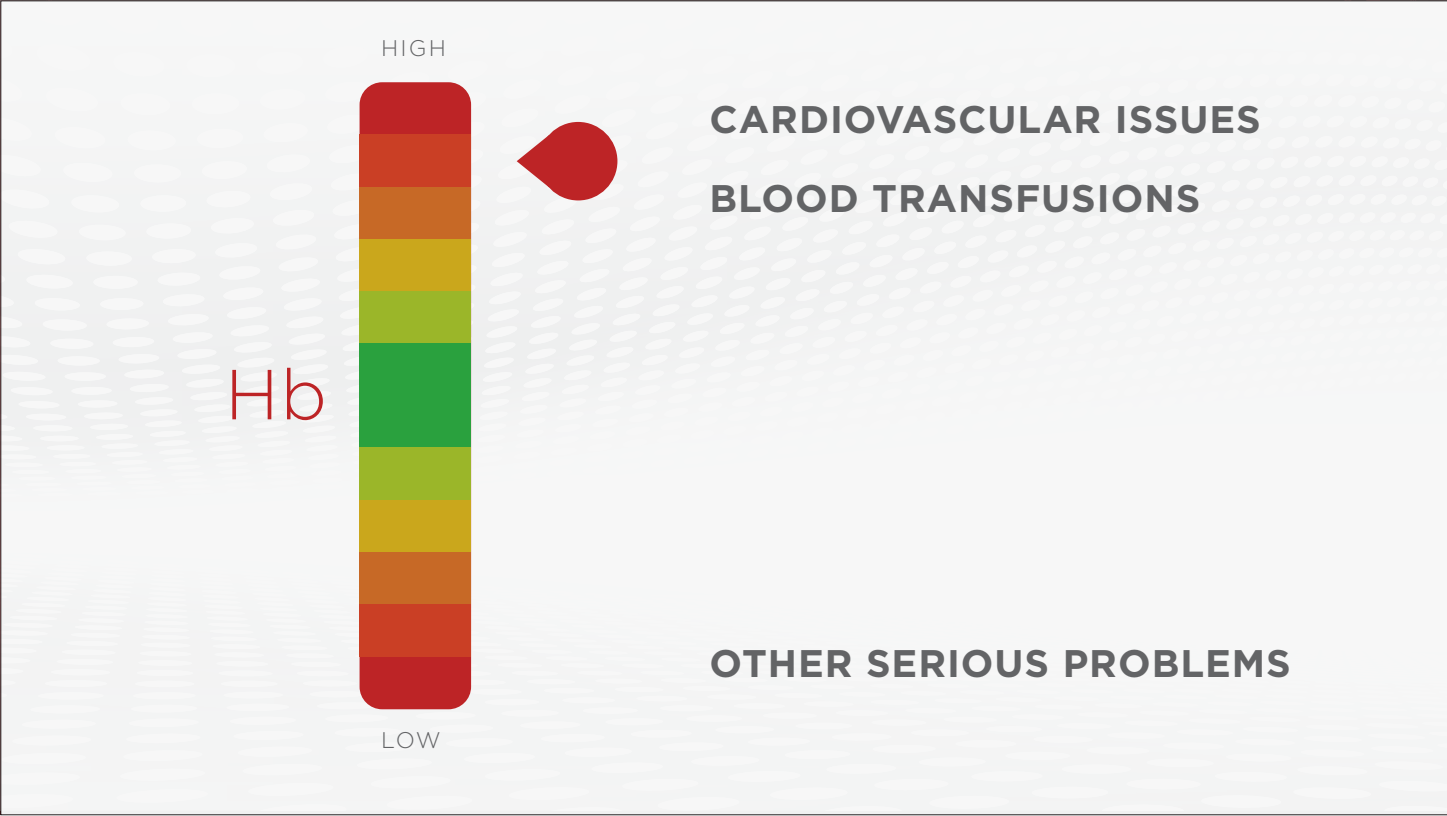
In this video, we'll look at the different factors that may affect hemoglobin (Hb) levels in patients with anemia due to chronic kidney disease (CKD), and how to assess trends in lab values.

ASSESSING Hb TRENDS TO OPTIMIZE PATIENT OUTCOMES

A look at factors that may affect Hb levels and how to evaluate trends in lab values

ANIMATION NOTES:

Title animates on. Subtext animates on. Red blood cell background is a video file.
[<https://premier.shutterstock.com/video/detail-20548588/3d-animation-of-red-blood-cells-flowing-through-artery>]



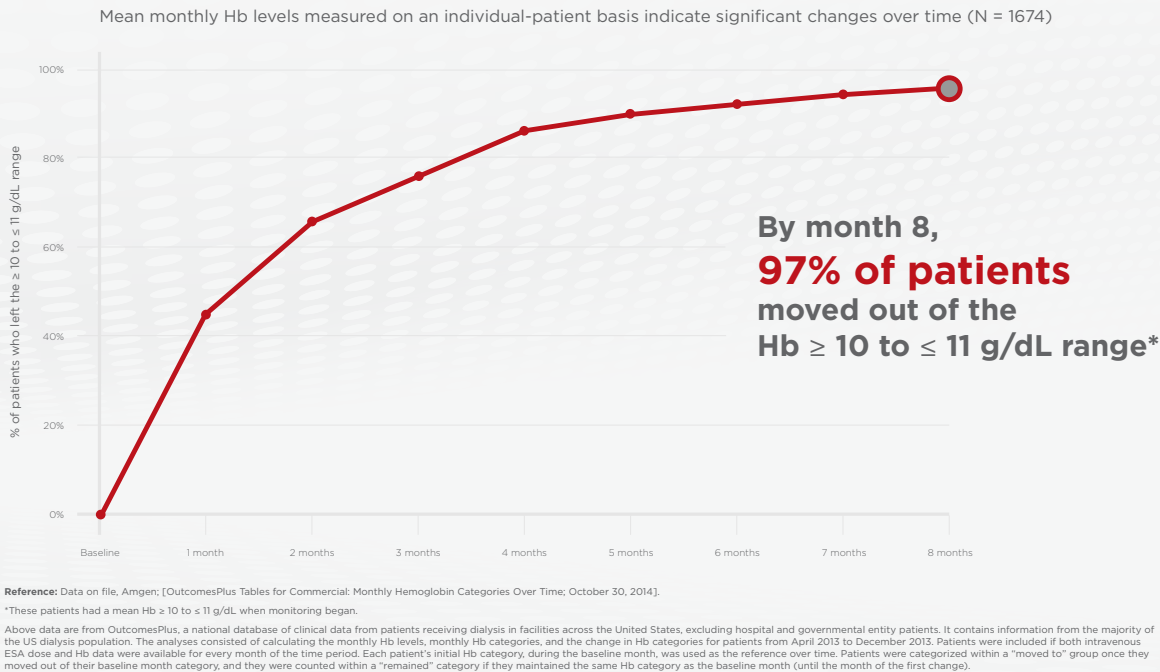
It's important to keep Hb levels within range in order to optimize patient outcomes. Hb that is too high or too low could lead to cardiovascular issues or require blood transfusions, or cause other serious problems.

ANIMATION NOTES:

Hb level animates on, blood drop indicator moves up and down. When indicator is high, 2 bullets at top animate on as VO speaks. When indicator is low, 1 bullet at bottom animates on as VO speaks.

We know that patients on dialysis frequently experience changes to their Hb levels.

This chart shows that, in an 8-month study of dialysis patients across the US, the vast majority - 97% - had a mean monthly Hb change that caused them to move out of their baseline range.



ANIMATION NOTES:

Chart animates on. Take-away bullet animates on as VO speaks.

So what are the various factors that may affect a patient's Hb levels?

A microscopic view of numerous red blood cells, appearing as biconcave discs, set against a dark red background. The cells are in various stages of focus, creating a sense of depth.

**What are the different factors that
may affect a patient's Hb levels?**

ANIMATION NOTES:

Text animates on. Red blood cell background is a video file.

- 1. Individual patient factors,
- 2. Unpredictable clinical events, and
- 3. Practice patterns

3 factors that may affect Hb levels



**INDIVIDUAL
PATIENT FACTORS**



**UNPREDICTABLE
CLINICAL EVENTS**



**PRACTICE
PATTERNS**

ANIMATION NOTES:

Title animates on. Icons and factor names animate on as VO speaks.

Looking at the first group - patient factors - what are these?



FACTOR TYPE 1:
INDIVIDUAL PATIENT FACTORS

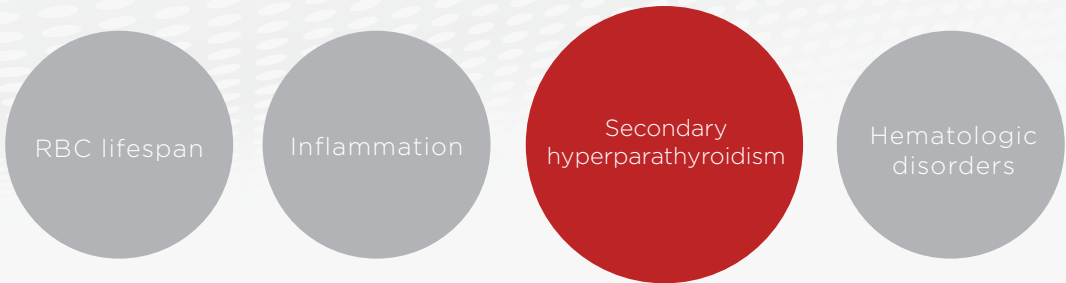
ANIMATION NOTES:

Arrow slides in from left. Text and icon animate on. Background texture is a video file.

[<https://premier.shutterstock.com/video/detail-30126370/flowing-abstract-grey-white-waves-graphic-motion-design-video-animation-ultra-hd-4k-3840x2160>]

Well, they may include things like the lifespan of a patient's red blood cells, inflammation, secondary hyperparathyroidism (HPT), or hematologic disorders.

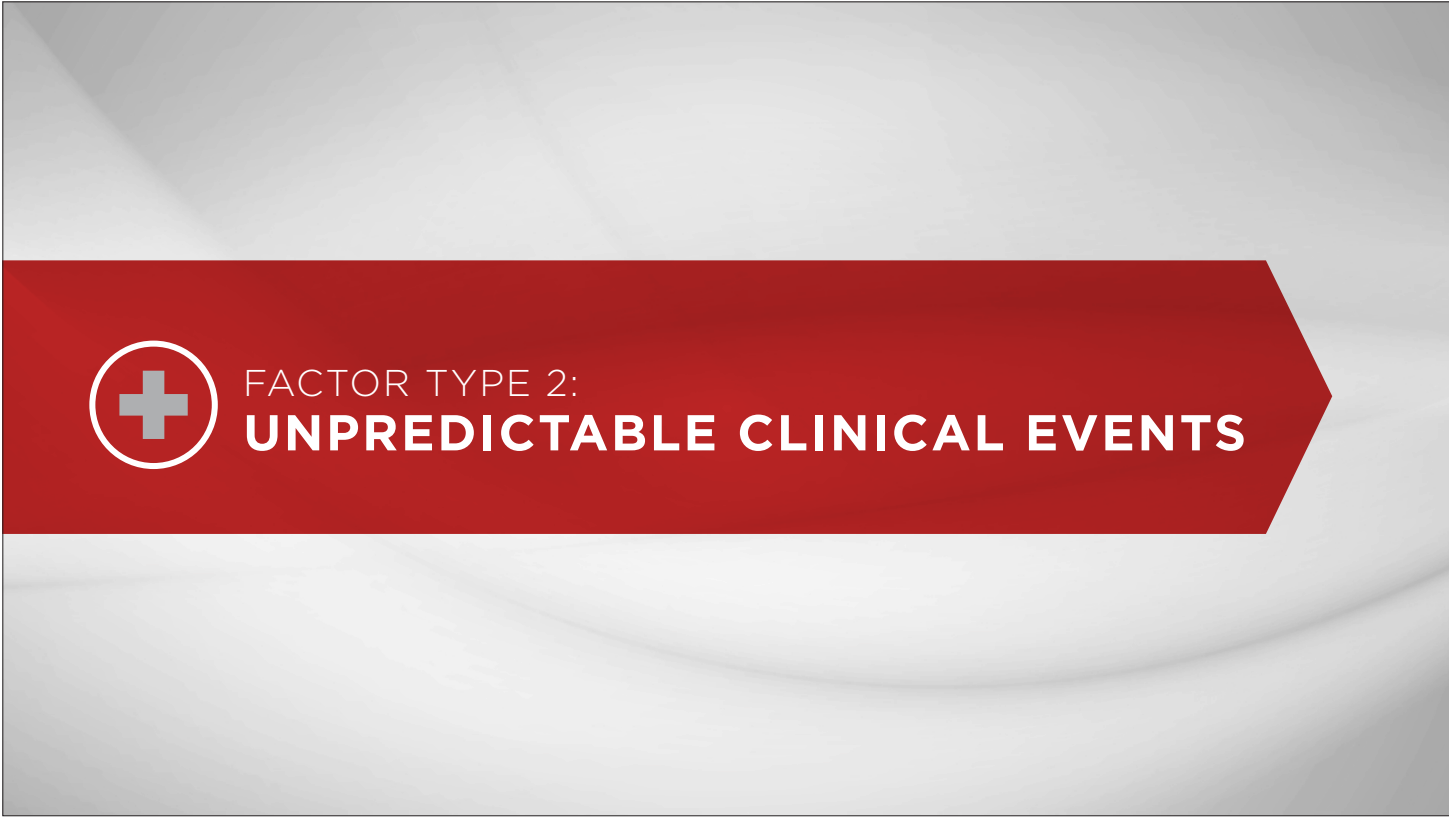
Individual patient factors



ANIMATION NOTES:

Title animates on. All circles animate on. As each “individual patient factor” is read by VO, that circle will turn red and enlarge.

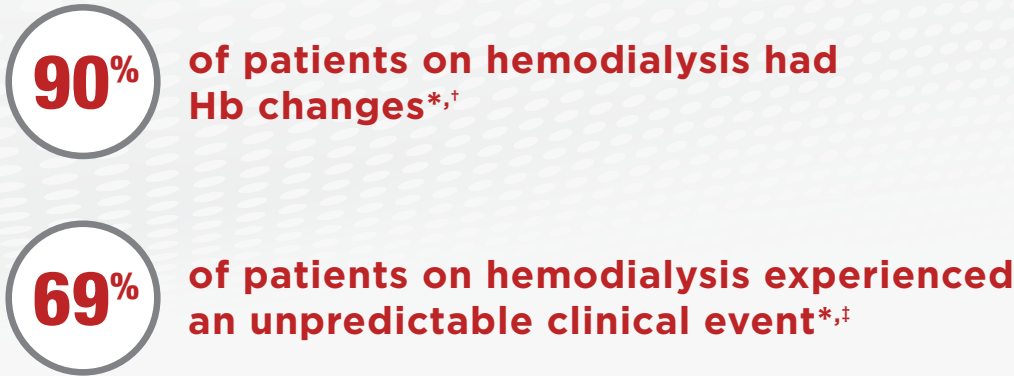
The second group of factors that might impact Hb is unpredictable, or intercurrent, clinical events.



ANIMATION NOTES:

Arrow slides in from left. Text and icon animate on. Background texture is a video file.

In a 6-month study of patients with CKD on dialysis, 90% saw changes in their Hb levels, while 69% experienced unpredictable clinical events. So there appears to be a correlation.



Reference: Gilbertson DT, Peng Y, Bradbury B, Ebben JP, Collins AJ. Hemoglobin level variability: anemia management among variability groups. *Am J Nephrol*. 2009;30(6):491-498.

^{*}Based on a 6-month, retrospective analysis of all Medicare primary payer hemodialysis patients who survived and had ESA claims in the first 6 months of 2004 (N = 159,720).

^{*}Patients were classified as "experienced changes in Hb" if their Hb levels fluctuated during the 6-month period in the following patterns: low to intermediate, intermediate to high, or low to high.

[‡]Unpredictable clinical events patients experienced during the 6-month study included hospitalization, vascular access insertions/complications, or receipt of IV antibiotics (ie, more serious infections).

ANIMATION NOTES:

As VO speaks, each stat (number icon and text) animate on.

Unpredictable clinical events could include hospitalization, inflammation, infection, or one or more comorbidities.

Unpredictable clinical events can include:



Hospitalization



Inflammation



Infection



Comorbidities

References:
Ebben JP, Gilbertson DT, Foley RN, Collins AJ. Hemoglobin level variability: associations with comorbidity, intercurrent events, and hospitalizations. *Clin J Am Soc Nephrol.* 2006;1(16):1205-1210.
Chan KE, Lazarus JM, Wingard RL, Hakim RM. Association between repeat hospitalization and early intervention in dialysis patients following hospital discharge. *Kidney Int.* 2009;76(3):331-341.
Bradbury BD, Crichtlow CW, Weir MR, Stewart R, Krishnan M, Hakim RH. Impact of elevated C-reactive protein levels on erythropoiesis-stimulating agent (ESA) dose and responsiveness in hemodialysis patients. *Nephrol Dial Transplant.* 2009;24(3):919-925.
Solid CA, Foley RN, Gilbertson DT, Collins AJ. Perihospitalization hemoglobin-epoetin associations in U.S. hemodialysis patients, 1998 to 2003. *Hemodial Int.* 2007;11(4):442-447.

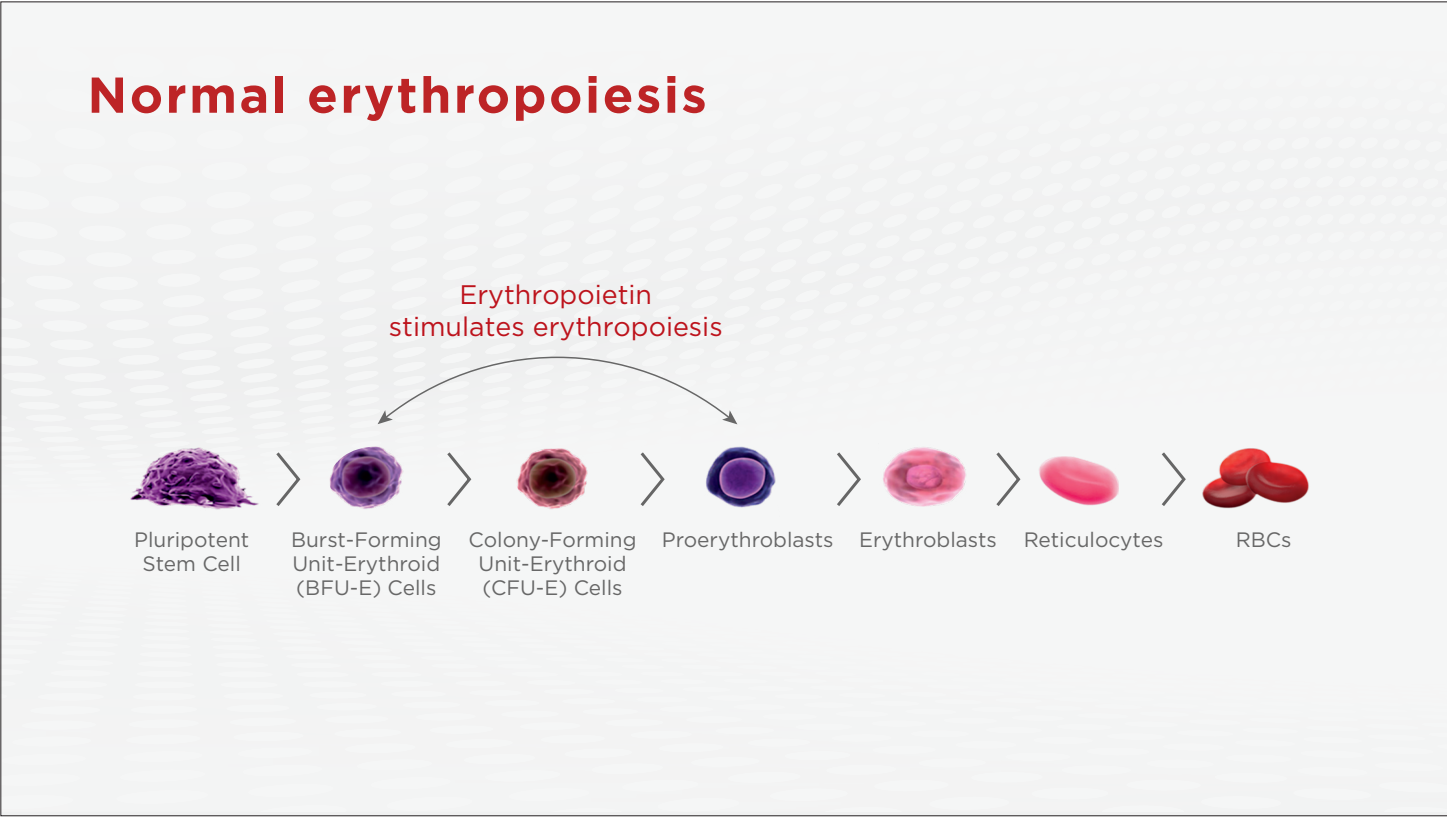
ANIMATION NOTES:

Title animates on. As VO speaks, each icon and event animates on.

So how do these factors affect Hb?

In the case of inflammation and infection, these conditions may inhibit the production of red blood cells, the process known as erythropoiesis.

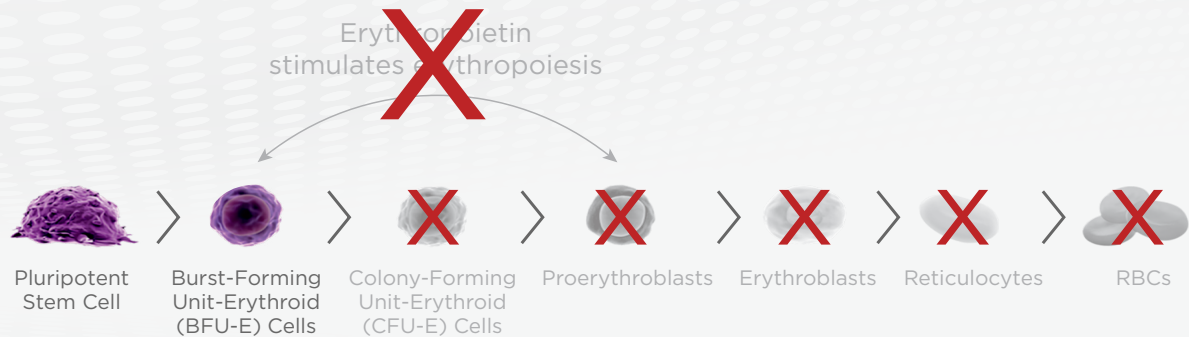
The image here shows the difference between normal and impaired erythropoiesis.



ANIMATION NOTES:

Title animates on. Diagram animates on from left to right.


Impaired erythropoiesis




ANIMATION NOTES:

Title transistions to new copy. Images grey out. Red x's appear.


Comorbidities can include:




Initiation of Dialysis




Vascular Disease




Tooth Abscess




GI Bleed




Interdialytic Weight Gain




Hospitalization




Arthritis Flare




Medications




Iron Deficiency



Pneumonia



Foot Ulcer



Pure Red Cell Aplasia

As for comorbidities, these might include anything from iron deficiency or GI bleed to vascular disease, pneumonia, arthritis, pure red cell aplasia, or interdialytic weight gain.

Even a tooth abscess or foot ulcer could affect a patient's Hb levels.

The initiation of dialysis might also have an effect, as may the use of other medications including certain antibiotics and analgesics.

ANIMATION NOTES:

Title animates on. Images animate on (pop) and comorbidities animate on (slide). As VO speaks certain ones, those enlarge.

LAB MEASUREMENTS

	Hb (g/dL)	TSAT (%)	FERRITIN (ng/mL)	TIBC (ug/dL)	RETICULOCYTE COUNT (% of total RBC count)	WBC (cells/mm ³)	ALBUMIN (g/dL)	Kt/V	URR
Reference Values	Individualize	> 20%	≥ 100	250-460	0.5%-1.5%	5,000-10,000	≥ 4.0	> 1.2	≥ 65
Chronic blood loss	▼	▼	▼		▲				
Hemolysis	▼	▲	▲		▲ or ▼				
Infection	▼	▼	▲	▼		▲	▼		
Inflammation	▼	▼	▲	▼		▲	▼		
Iron deficiency absolute	▼	▼	▼	▲					
Iron deficiency functional	▼	▼	▲	▼		▲	▼		
Secondary HPT	▼								
Inadequate dialysis	▼							< 1.2	65%
Malnutrition	▼						▼		

Kt/V is a formula for measuring dialysis adequacy, where K = dialyzer clearance, t = time, and V = volume of urea distribution in a patient's body.

If a patient has comorbidities, we should consider the lab trends linked with those conditions that may impact Hb. This way we can manage the underlying cause of the Hb changes.

Lab trends might include the ferritin or albumin measurements for conditions such as chronic blood loss, hemolysis, infection, inflammation, iron deficiency, or malnutrition.

ANIMATION NOTES:

Chart (minus arrows) animate on. Arrows animate on. Left column is “highlighted” when VO speaks.

Let's take a look at chronic blood loss, which is a common condition. In this case, we'd want to measure for Hb, transferrin saturation, ferritin, total iron binding capacity, reticulocyte count, white blood cell count, albumin, ratio of K multiplied by t over V, and urea reduction ratio.

LAB MEASUREMENTS

	Hb (g/dL)	TSAT (%)	FERRITIN (ng/mL)	TIBC (ug/dL)	RETICULOCYTE COUNT (% of total RBC count)	WBC (cells/mm ³)	ALBUMIN (g/dL)	Kt/V	URR
Reference Values	Individualize	> 20%	≥ 100	250-460	0.5%-1.5%	5,000-10,000	≥ 4.0	> 1.2	≥ 65
Chronic blood loss	▼	▼	▼		▲				
Hemolysis	▼	▲	▲		▲ or ▼				
Infection	▼	▼	▲	▼		▲	▼		
Inflammation	▼	▼	▲	▼		▲	▼		
Iron deficiency absolute	▼	▼	▼	▲					
Iron deficiency functional	▼	▼	▲	▼		▲	▼		
Secondary HPT	▼								
Inadequate dialysis	▼							< 1.2	65%
Malnutrition	▼						▼		

Kt/V is a formula for measuring dialysis adequacy, where K = dialyzer clearance, t = time, and V = volume of urea distribution in a patient's body.

ANIMATION NOTES:

All chart (except for the chronic blood loss row and up) fades to highlight. Red row highlights as VO speaks.

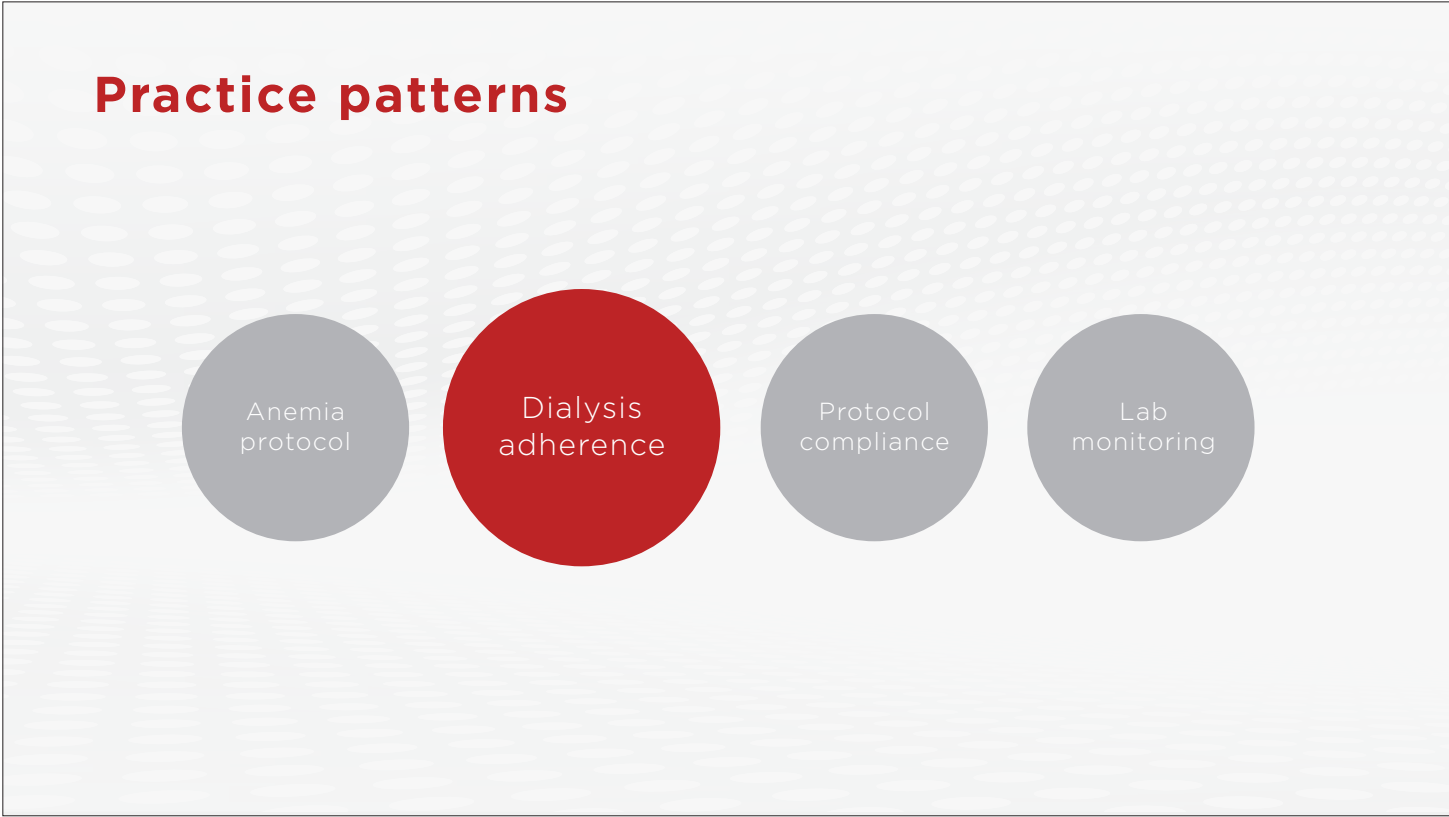
Our final group of factors that could affect a patient's Hb levels is what goes on inside the dialysis center where patients are being treated.



ANIMATION NOTES:

Arrow slides in from left. Text and icon animate on. Background texture is a video file.

Practice patterns may include the anemia protocol, dialysis treatment adherence, protocol compliance, and lab monitoring.



ANIMATION NOTES:

Title animates on. All circles animate on. As each “practice pattern” is read by VO, that circle will turn red and enlarge.

Which of these factors may be associated with a change in Hb levels?



**INDIVIDUAL
PATIENT FACTORS**



**UNPREDICTABLE
CLINICAL EVENTS**



**PRACTICE
PATTERNS**

Having looked at the different factors that may affect a patient's Hb levels, we must evaluate which of those elements may be associated with the change in Hb levels.

ANIMATION NOTES:

Title animates on. Icons and factor names animate on as VO speaks.

Questions to consider when evaluating Hb levels

Is there a change in the patient's status?

Is the change congruent with the patient's clinical picture?

Is there a trend in the lab value?

What is the rate of change in the lab value?

How does the lab value relate to other lab parameters?

Do you suspect that the results could be inaccurate?

Are there any other factors that may account for the result?

There are several questions we should ask. For example, is there a change in the patient's status and is this congruent with the patient's clinical picture? Is there a trend in the lab value – what does this look like, how fast is it moving, and how does the lab value relate to other lab parameters?

On the other hand, do you suspect there's a mistake in the results? Or is there anything else that may account for them?

ANIMATION NOTES:

Title animates on. All circles animate on. As each “question” is read by VO, that circle will turn red and enlarge.

By using a systematic approach, we can find opportunities to better manage anemia for our patients with CKD.

A microscopic view of numerous red blood cells, appearing as biconcave discs, set against a dark red background. The cells are in various stages of focus, creating a sense of depth.

**How can we improve
anemia management?**

ANIMATION NOTES:

Text animates on. Red blood cell background is a video file.

A systematic approach to improve anemia management



Monitor Hb **TRENDS**
over time

It's a threefold matter of:

1. Monitoring Hb trends over time – that's weekly at initiation and at every dose adjustment until Hb is stable, and then at least monthly when Hb is stable

ANIMATION NOTES:

Title animates on. Icon and text animate on as VO speaks.

By the way, did you know that 82% of monitoring practices occur within 2 weeks, according to a national database?

A systematic approach to improve anemia management

TREND

Monitor Hb **TRENDS** over time

82%

of monitoring practices occur within 2 weeks*

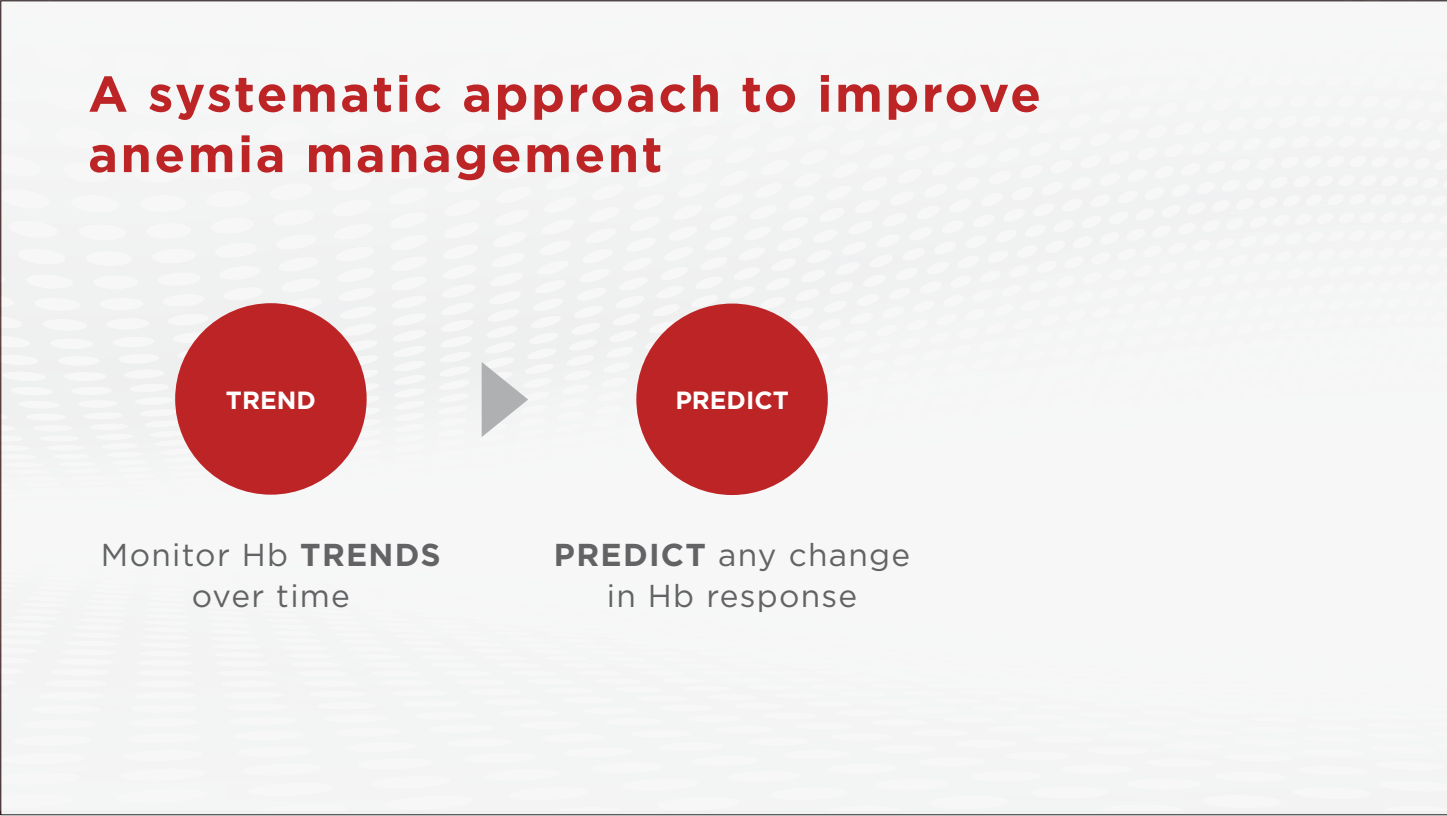
Reference: Data on file, Amgen; [ESA OutcomesPlus Monthly Report; May 2017].

*Data are from OutcomesPlus, a national database of clinical data from patients receiving dialysis in facilities across the United States, excluding hospital and governmental entity patients. It contains information from the majority of the US dialysis population. The analysis consisted of calculating an average quarterly frequency of Hb monitoring from Q1 2014 to Q2 2017 from MDOs.

ANIMATION NOTES:

Stat animates on.

2. Predicting any change in Hb response – this means assessing iron status and causes of low or high Hb, and



ANIMATION NOTES:

Arrow and next icon and text animate on as VO speaks.

A systematic approach to improve anemia management



Monitor Hb **TRENDS**
over time

PREDICT any change
in Hb response

INTERVENE to address
Hb changes

3. Intervening to address Hb changes as appropriate – this could mean identifying and managing factors affecting Hb, as well as factors associated with anemia due to CKD. It may also mean individualizing anemia management dosing, using the lowest dose sufficient to reduce the need for blood transfusion.

ANIMATION NOTES:

Arrow and next icon and text animate on as VO speaks.

Working as a lab team



Implement clinician-prescribed interventions following receipt of lab values to minimize cycle time



Educate staff members on the trends in lab results that should be escalated to the prescriber



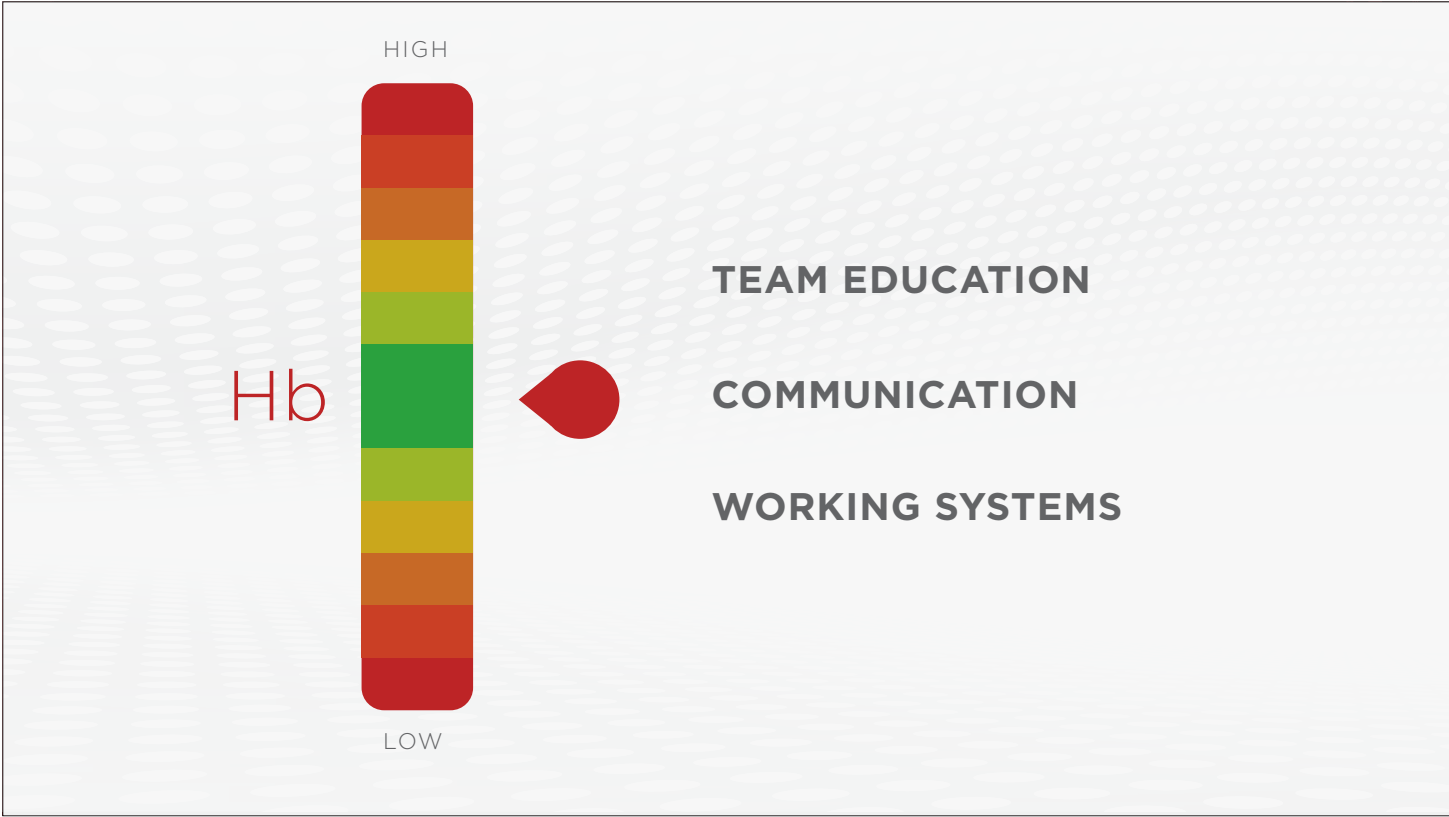
Implement a process and timeline for notifying the prescriber about lab results that may not be covered by protocol

We should also find a system for working as a lab team. For example, it's important to educate your staff on trends that should be reported to the prescriber, and to implement a process and timeline for notifying the prescriber about lab results that may not be covered by normal protocol.

ANIMATION NOTES:

Title animates on. As VO speaks, each bullet (with checkmark) animates on.

With team education, communication, and working systems, we can manage our patients' treatment and keep their Hb levels within range to achieve the best possible outcomes.



ANIMATION NOTES:

Hb level animates on, blood drop indicator moves up and down. When indicator settles in middle, 3 bullets animate on as VO speaks.

As a recap of what we’ve learned, here are some short questions for you:



ANIMATION NOTES:

Text animates on. Red blood cell background is a video file.

What are the three factor types that might affect a patient's Hb levels?

1. What are the three factor types that might affect a patient's Hb levels?

- 1. Individual patient factors,**
- 2. Unpredictable clinical events,**
- and**
- 3. Practice patterns**

ANIMATION NOTES:

Arrow slides in from left. Number and question animate on. Pause for audience to think. Answer animates on, one line at a time. No VO.

How might inflammation and infection affect Hb levels?

2. How might inflammation and infection affect Hb levels?

They may inhibit the production of red blood cells, the process known as erythropoiesis.

ANIMATION NOTES:

Arrow slides in from left. Number and question animate on. Pause for audience to think. Answer animates on, one line at a time. No VO.

What kind of practice patterns might impact a patient's Hb?

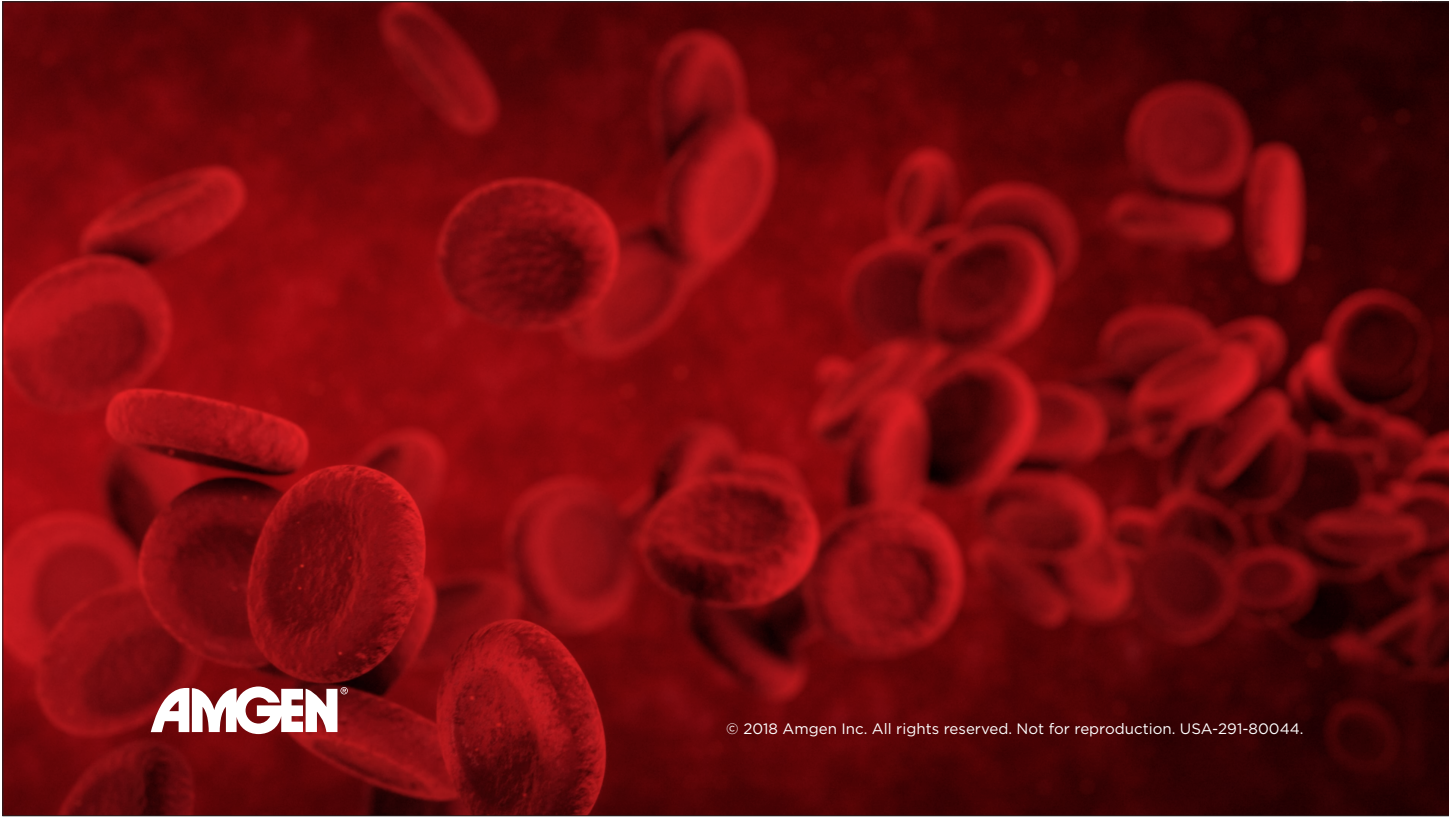
3. What kind of practice patterns might impact a patient's Hb?

- **Anemia protocol**
- **Adherence**
- **Compliance**
- **Lab monitoring**

ANIMATION NOTES:

Arrow slides in from left. Number and question animate on. Pause for audience to think. Answer animates on, one line at a time. No VO.

Thank you for watching. This completes our video on assessing Hb trends to optimize patient outcomes.



ANIMATION NOTES:

Text and logo animate on. Red blood cell background is a video file.