

A microscopic view of red blood cells (erythrocytes) in the foreground, appearing as bright red, biconcave discs. In the background, there are green, leaf-like structures, possibly representing the source of iron or a natural setting. The overall lighting is soft, highlighting the texture of the cells and the greenery.

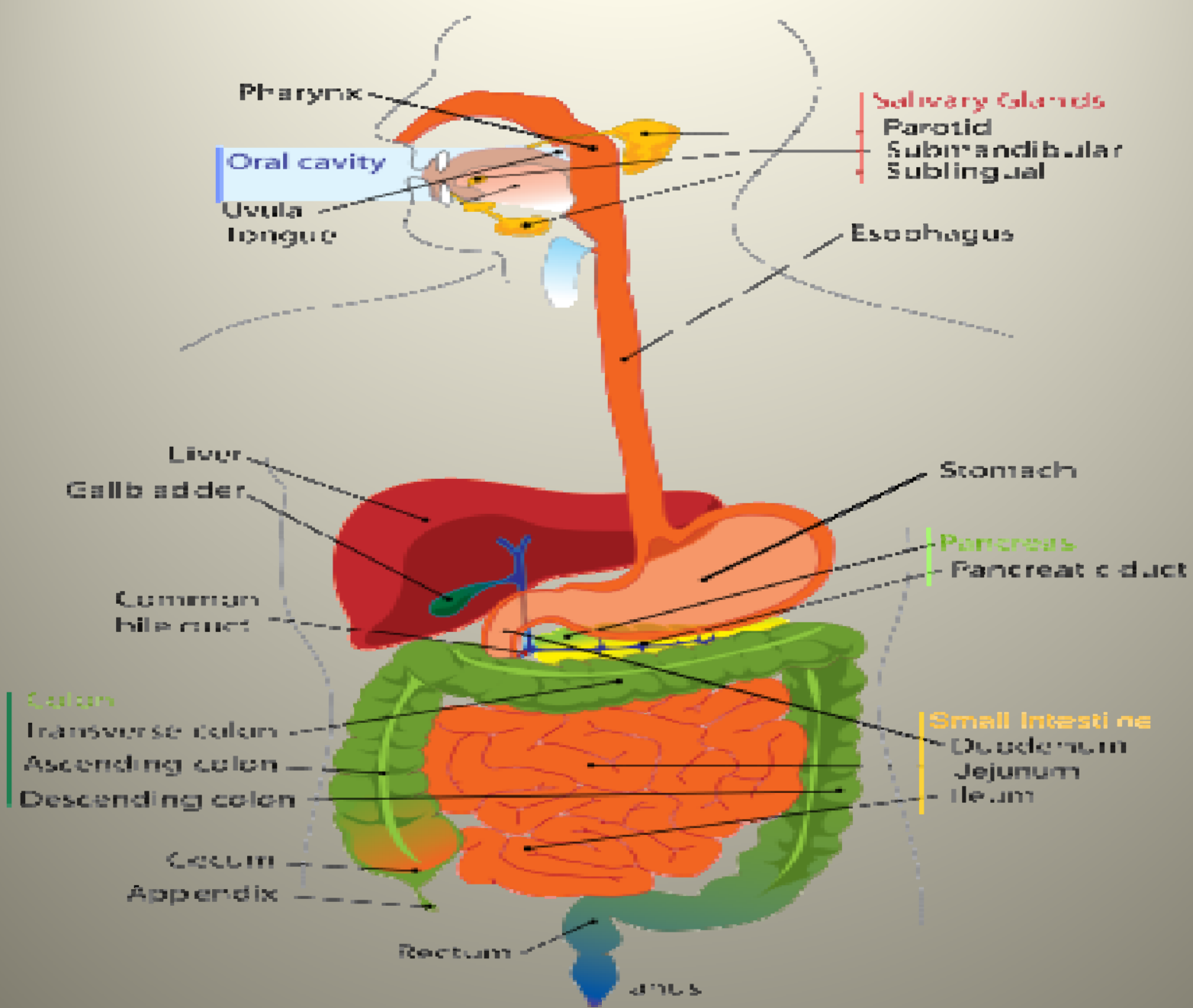
USE OF ERYTHROPOIETIN  
IN ANEMIA,  IS IT REALLY  
A **BAD BOY?**

Presented By

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- Simple Measures for dealing with anemias can
- sometimes be quite a vexing problem.
- Working through the myriad of comorbid conditions can often be a difficult task
- Lets begin with a basic approach, then discuss issues that will affect some of our treatment options by March 2011.

- Starting with an assessment of the nutritional component of the anemia is the first step in the process.
- Current trends for bariatric procedures, altering the usual sites of absorption of critical nutrients as well as identification of any abdominal procedures that may have shortened the gut or completely removed vital segments necessary for absorption



- An accurate nutritional diary is critical to understanding inadvertent deficiencies due to poor dietary habits, vegetarian preferences without understanding of needed nutrients, meat and potatoes kind of a person versus Mrs. Smith preferring a cup of tea and toast.
- Attitudes regarding fruits and vegetables can sometimes be surprising.

- Special needs in nutrition are many times overlooked as well.
- The high school athlete running 100 miles weekly, living on coke and potato chips.
- The mother of three, with heavy menstrual flow and stressors of still nursing her 9 month old infant.
- Then there is the popular tapeworm diet.



# ANEMIA WORKUP

- Determine the physiologic response-is it regenerative versus hyporegenerative
- Identify cell size to further narrow the assessment
- Regenerative-hemolysis, blood loss, response to treatment
- Hyporegenerative-every cell size always consider chronic disease and sideroblastic

## MDS: Clinical Presentation

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- Hematologically diverse
  - Anemia, thrombocytopenia, neutropenia
- Ineffective hematopoiesis
- Disease of older individuals
- Potential evolution to AML ~30%

# Patient Evaluation and Diagnosis

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- H&P
  - Historical laboratory data, episodes of illness, evaluation of comorbid conditions, and concomitant medications
- Blood tests
  - CBC, differential, reticulocyte count, MCV
  - Iron, ferritin, TIBC
  - RBC folate, B<sub>12</sub>
  - TSH, LDH
  - Serum erythropoietin level (prior to RBC transfusion)
  - HLA typing (if HSCT considered or for platelet support)
  - Consider paroxysmal nocturnal hemoglobinuria screening
- BM biopsy and aspirate
  - Iron stain (increased iron stores)
  - Hematopathology (% blasts, cellularity, presence of ALIP, dysplastic features, ringed sideroblasts)
  - Cytogenetics



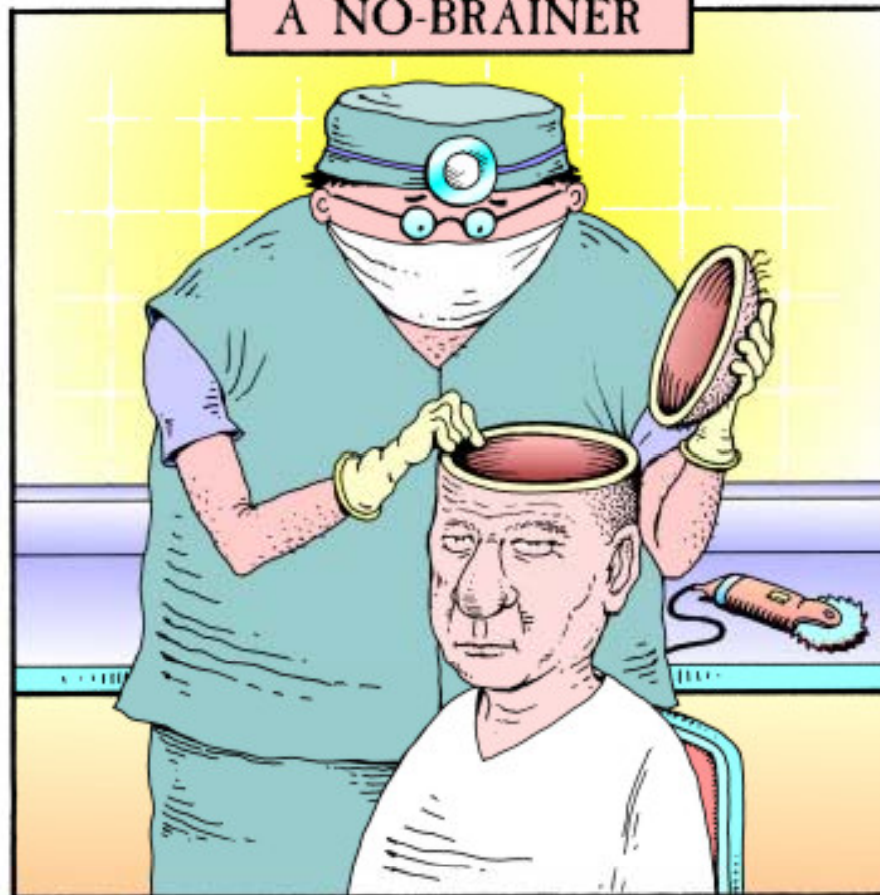
Have you evaluated all organ systems?

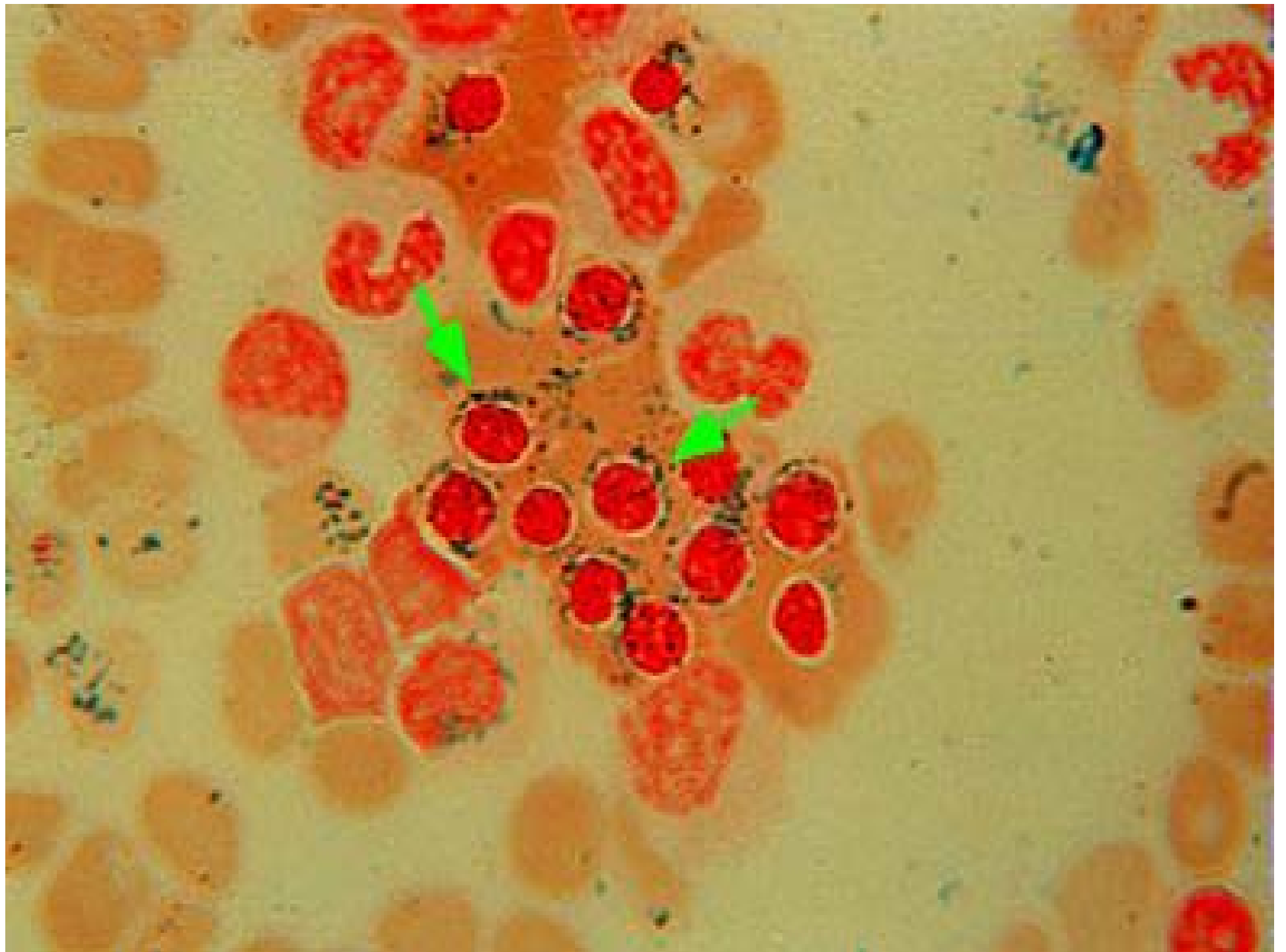
## FAB Classification and Survival

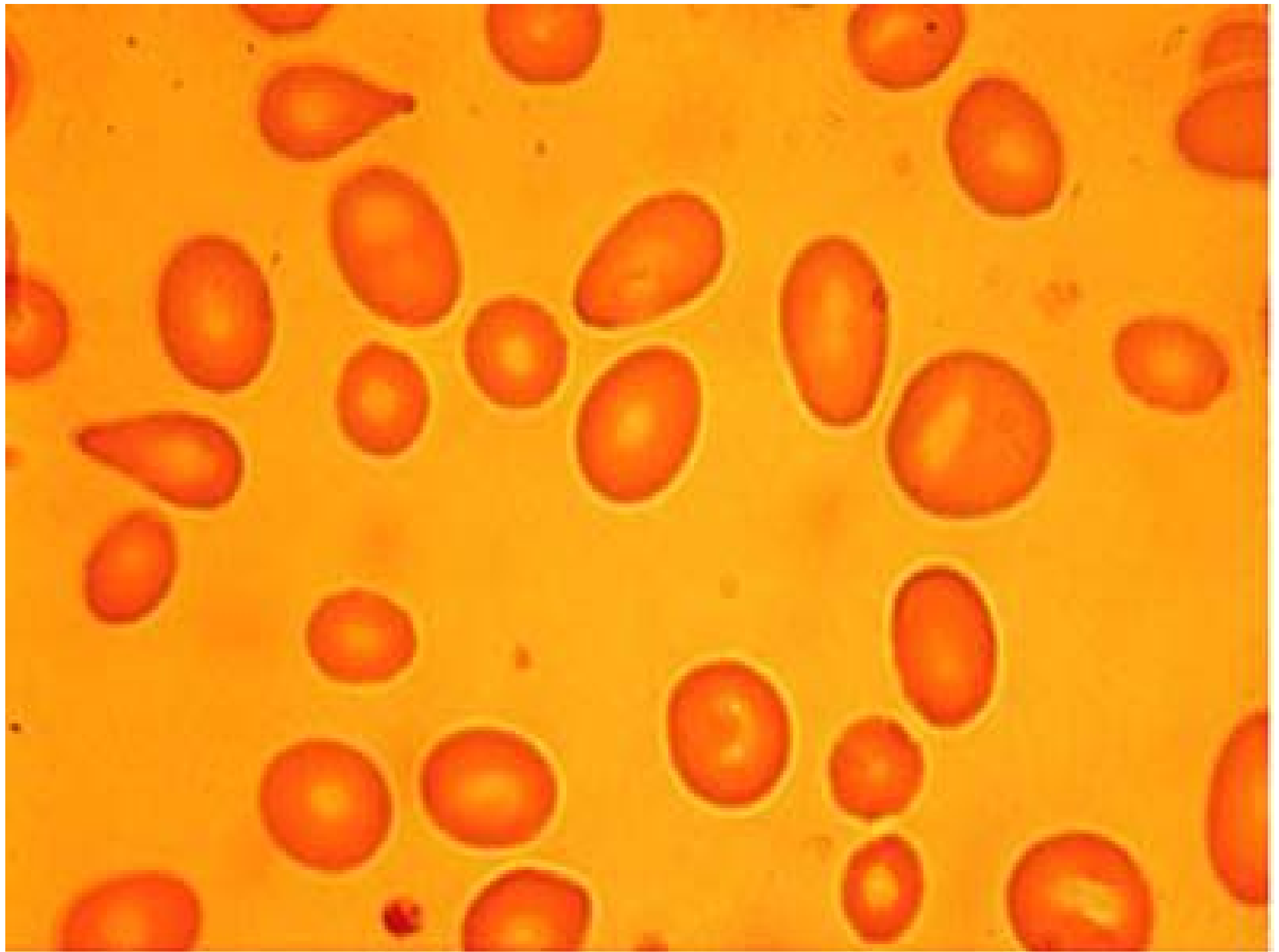
FAB Classification	Median Survival, mo (range)	Leukemic Transformation, % (range)
RA (refractory anemia)	37 (19–64)	11 (0–20)
RARS (RA with ringed sideroblasts)	49 (21–76)	5 (0–15)
CMML (chronic myelo-monocytic leukemia)	22 (8–60)	20 (3–55)
RAEB (RA with excess blasts)	9 (7–15)	23 (11–50)
RAEB-t (RA with excess blasts in transformation)	6 (5–12)	48 (11–75)

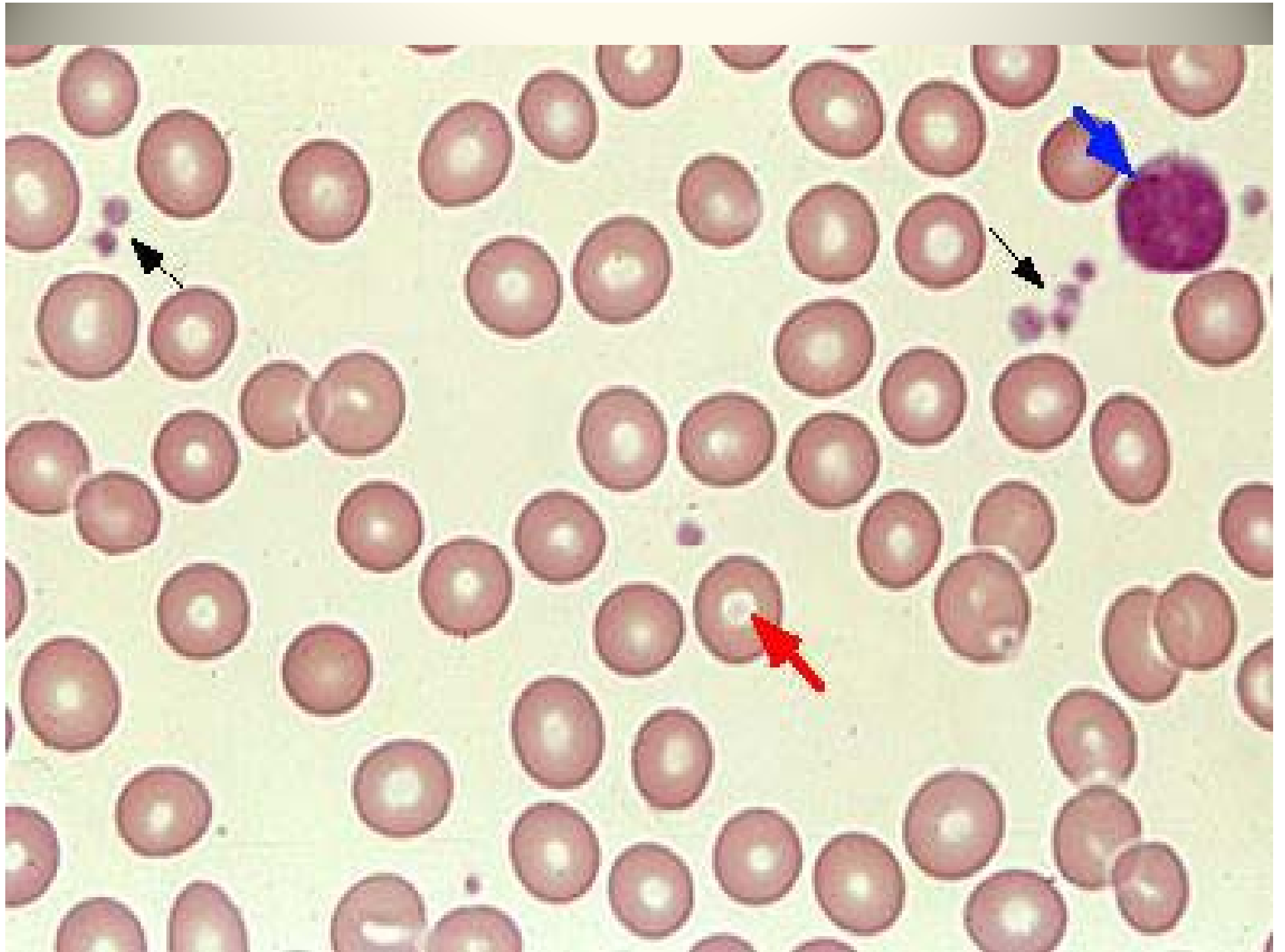
Bennett JM et al. *Br J Haematol*. 1982;51:189  
Gallagher A et al. *Haematologica*. 1997;82:191

A NO-BRAINER











Agua con el agua

Agua con el agua

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03.17.2009 09:50

- When do we consider use of erythropoietin and what is all the excitement about?

- Erythropoietin is indicated for the treatment of anemia due to metastatic carcinoma on chemotherapy that is considered non-curative and decreased erythropoietin levels in CKD.
- Ineffective erythropoiesis seen in myelodysplastic syndromes can be considered for erythropoietin use as well.

# New Regulations for use of erythropoietin

- ESA APPRISE Oncology Program
- A Risk Evaluation and Mitigation Strategy (REMS) is the program established by the FDA in 2007 that requires drug manufacturers to develop and implement a drug safety program for the use of erythropoietin
- WHY?

- ESA's in some clinical studies have shortened overall survival and/or increased the risk of tumor progression or recurrence .
- The most compelling evidence was identified in breast cancer, non-small cell lung cancer, head and neck cancers, lymphoid cancers and cervical cancers.

- **Anemia due to treatment for cancer**
- In March 2008, a panel of advisers for the [U.S. Food and Drug Administration](#) (FDA) supported keeping ESAs from [Amgen](#) and [Johnson & Johnson](#) on the market for use in cancer patients. The FDA has focused its concern on study results showing an increased risk of death and [tumor](#) growth in chemo patients taking the anti-anemia drugs. According to the FDA, evidence for increased rates of mortality exist in various cancers, including breast, lymphoid, cervical, head and neck, and non-small-cell lung cancer<sup>[15]</sup>

- Additional complications associated with use of ESA's have been increased thromboembolic events linked with the use in cardiac cases, and instances where hemoglobin levels were taken higher than the recommended values

- What is needed to prescribe erythropoietin for my patients?
- [www.esaapprise.com](http://www.esaapprise.com)
- [www.FDA.gov](http://www.FDA.gov)

# SO LETS GET STARTED



Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs

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## ESA (erythropoiesis stimulating agent) APPRISE Oncology Program Training Module for Healthcare Providers (HCPs) who Prescribe or Prescribe and Dispense ESAs for Patients with Cancer

This ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs) Oncology Program Training Module is the core requirement for enrollment within the ESA APPRISE Oncology Program, developed by Amgen and Centocor Ortho Biotech Products, L.P. The ESA APPRISE Oncology Program is part of a Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration (FDA) has determined that REMS is necessary for ESAs to ensure that the benefits of a drug outweigh the risks of shortened overall survival and/or increased risk of tumor progression or recurrence as shown in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.

### The goals of the REMS for Aranesp® and Epogen®/Procrit® are:

- To support informed decisions between patients and their healthcare providers (HCPs) who are considering treatment with Aranesp® or Epogen®/Procrit® by educating them on the risks of Aranesp® or Epogen®/Procrit®.
- For treatment of patients with cancer, the goal of the REMS, as implemented through the ESA APPRISE Oncology Program, is to mitigate the risk of decreased survival and/or poorer tumor outcomes.

