

DIALYSATE-BASED IRON FOR END-STAGE RENAL DISEASE PATIENTS ON HEMODIALYSIS

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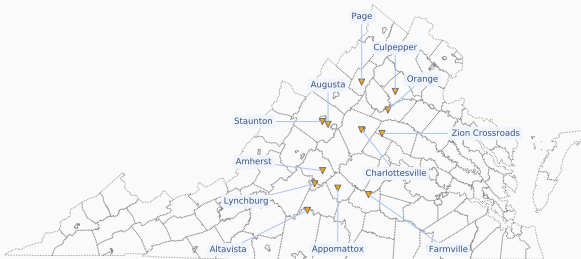
School of Data Science

KIDNEY DISEASE

- There are over 30 million Americans with some form of kidney disease
- End-Stage Renal Disease (ESRD) is the most severe form, affects over 650,000 individuals, and affects minorities more than whites¹
- Diagnosed when the kidney's abilities to cleanse toxins from the blood fall below 15%
- Treatment options are
 1. Dialysis
 2. Kidney transplant

UVA DIALYSIS

- UVA has its own dialysis system
 - 12 dialysis units across Virginia, ~1000 patients



- Not an extremely large patient population...
 - Dialysis patients account for 1% of the Medicare population but 7% of the budget

ESRD-INDUCED ANEMIA

- Patients with End-Stage Renal Disease (ESRD) typically have ESRD-induced anemia (a low red blood cell count)
- Erythropoiesis stimulating agents (ESAs): main class of drugs administered in order to obtain the target red blood cell levels
- Medicare guidelines suggest a goal where 90% of dialysis patients achieve target red blood cell levels (hemoglobin [Hgb] levels) of 10–12 g/dL
- Medications, like the ESAs used to treat anemia, are costly and used by ~80% of all patients

DOSING CHALLENGES

- Patient response to ESAs is highly variable
 - Red blood cell production seems to shut down when a patient is sick (inflammation, etc.)
 - Presence of other co-morbidities
 - Raw materials (e.g., iron) must be present to produce red blood cells
- Iron can be dosed intravenously (current standard) or administered through the dialysate

HEMODIALYSIS

- 3-4 hour session, 3 times a week (MWF or TTS)
- Blood is circulated through the dialyzer and cleaned (replaces the function of the kidneys)
- Dialysate is used to pull toxins from the blood into the dialysate through diffusion
- Dialysate is a solution of pure water, electrolytes and salts, such as bicarbonate and sodium

TRIFERIC FOR ANEMIA MANAGEMENT IN DIALYSIS PATIENTS



TRIFERIC is the first and only FDA-approved treatment indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).^{1,2}

<https://www.rockwellmed.com/our-technology/products/>

- 103 patients from 2 units in the UVA dialysis system
- All 103 patients had relevant data (Hgb values, etc.) for each of the 8 months
- Triferic starts after month 3: to the right of the yellow dotted line in the plots that follow
- We have data for
 - 3 months prior to initiation of Triferic
 - 5 months post initiation of Triferic

OVERALL QUESTION

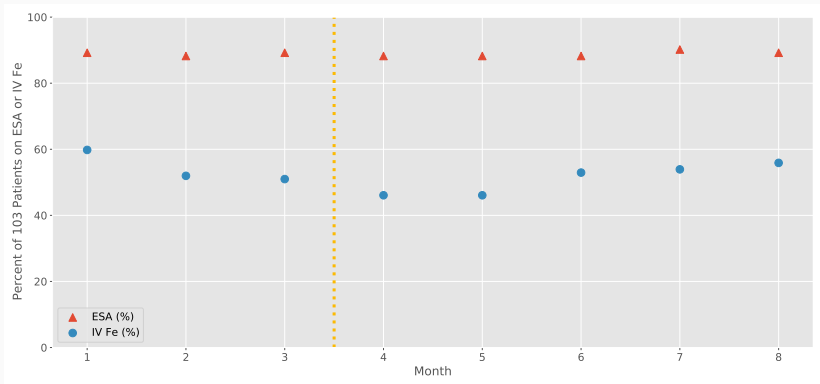
Did the Triferic result in:

1. A change in the percent of patients on ESA or IV Iron?
2. The average daily ESA or IV Iron dose?
3. The Hemoglobin or PSAT values?

Expectations:

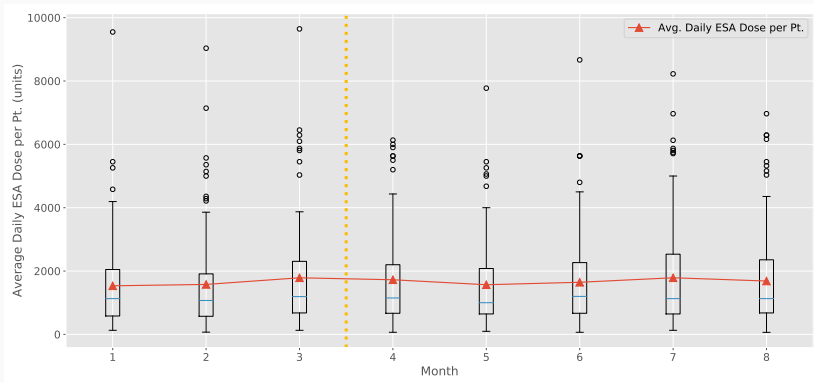
- Fewer patients on IV Iron
- Reduced average daily IV Iron dose
- Increased Hemoglobin and PSAT values

PERCENT OF PATIENTS ON ESA & IV IRON



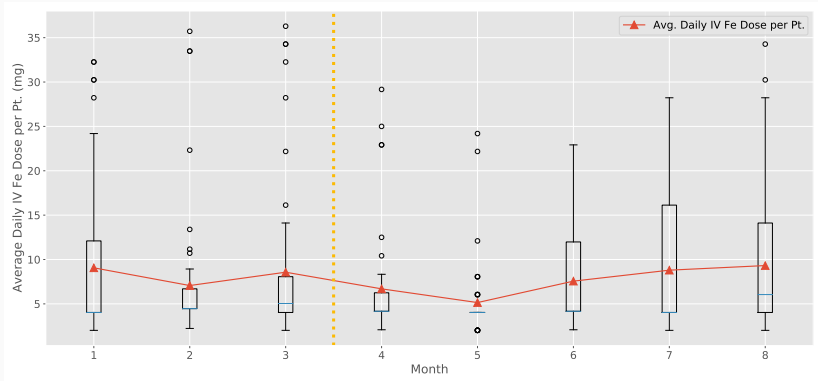
Percent is the percent of 103 patients each month.

ESA DOSE



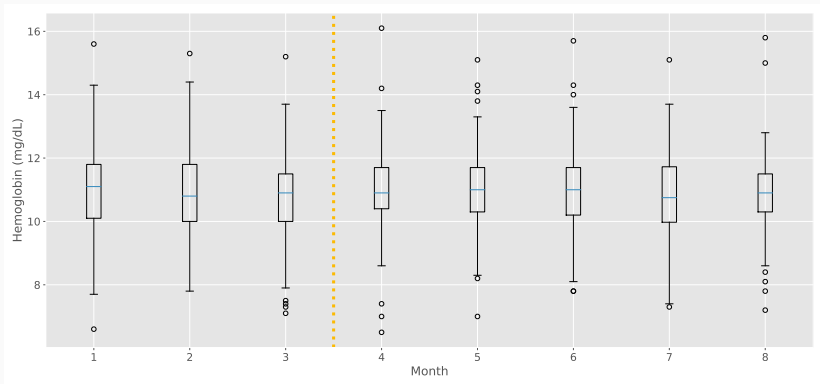
ESA dosing remains level throughout the timeframe.

IV IRON DOSE



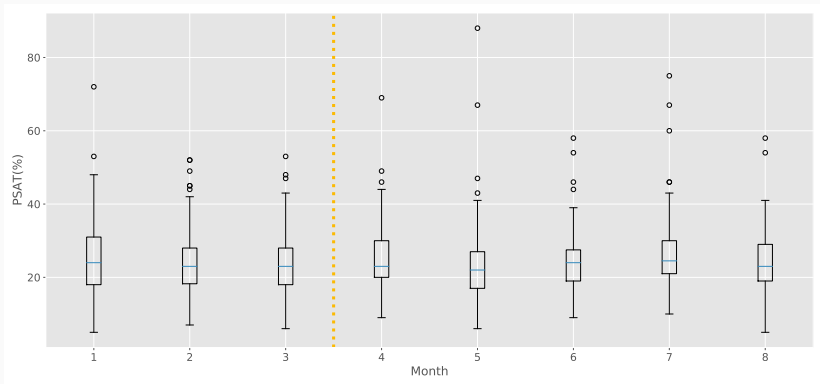
Dip in the mean IV Iron dose in months 4 and 5, but rebound thereafter.

MONTHLY HEMOGLOBIN



No appreciable change in Hemoglobins over the time frame.

PSAT



No appreciable change in PSATs over the time frame.

QUESTIONS

- Is this visual analysis enough to say Triferic did not work in the population?
- If not, what formal analysis should be carried out?
- Do you simply look at endpoints (January data versus August data) for the analysis?
- What things need to be controlled for in the analysis?

Questions?

REFERENCES

- [1] United States Renal Data System. 2016 USRDS annual data report: Epidemiology of kidney disease in the United States". Technical report, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2016.