Evidence of Practice Variation and Individualization in Anemia Management

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Introduction

- The objective of anemia management for hemodialysis (HD) patients is to use the lowest possible doses of erythropoiesis-stimulating agent (ESA) and iron to reduce risk of red blood cell transfusion.
- In June 2011, the FDA modified the label for ESAs and the Centers for Medicare and Medicaid Services (CMS) revised the Quality Incentive Program (QIP) anemia measure. The result explicitly removed a therapeutic hemoglobin (Hb) target from regulation and public policy.[1-3]
  - Physicians managing patients with dialysis-associated anemia were left only with the guidance to:
    - use the lowest dose of ESA to reduce the risk of red cell transfusion
    - avoid treating to a Hb target greater than 11 g/dL
    - by extension of the QIP measure, avoid ESA administration in patients with Hb above 12 g/dL
- The removal of a specified Hb target, coupled with a lack of dose adjustment recommendations on how to avoid transfusion and a black box warning to avoid Hb targets above 11 g/dL, created an opportunity for physicians to individualize ESA therapy according to practice preference and patient needs.[2,3]
- In the months that followed, publication of the KDIGO Anemia Guidelines[4] further encouraged individualization of care, recommending broad Hb windows for most patients and down-titration rather than holding ESA for above-target Hb.

Objective

To understand the effect of changes in ESA policy, regulation, and guidelines on physician practice in managing anemia in dialysis patients, we evaluated patterns of physician protocol selection and patient Hb outcomes in a large dialysis organization.

Methods

- For each in-center hemodialysis patient, physicians could choose to manage ESA dose adjustment either with or without a computer-assisted protocol, depending on physician practice preference and individual patient needs.
- Three computer-assisted anemia management protocols were developed, allowing maximum flexibility in physician preference while meeting individual patient needs.
- Protocol A:
  - Withhold ESA at Hb > 11.0 g/dL.
- Protocol B:
  - Down-titrate ESA at Hb = 11.1-11.5 g/dL, and
  - Hold ESA at Hb > 11.5 g/dL.
- Protocol C:
  - Down-titrate ESA at Hb > 11.0 g/dL, but
  - Hold ESA at Hb > 12 g/dL.
- All 3 protocols shared the same ESA dose adjustments at Hb concentrations ≤ 11.0 g/dL and the same laboratory orders to evaluate Hb weekly whenever ESA is on hold, otherwise twice monthly.

Results

Table 1. Protocol Orders Among Physicians Within the LDO Who Had ESA Orders in November 2012

	Protocol Orders Among Physicians Who Had ESA Orders
Protocol A only	4.6%
Protocol B only	29.6%
Protocol C only	22.9%
More than 1 protocol	30.7%
None	12.1%

- A high proportion of physicians (approximately 43%) used either no protocol or more than 1 protocol.

Table 2. Hemoglobin Outcomes

	Patient (%)	Mean Hb (g/dL)	Hb < 10 g/dL (%)
Protocol A	7.6	10.80	19.1
Protocol B	47.3	10.92	16.4
Protocol C	37.5	10.98	16.1
None	7.7	10.98	19.0

- Hb outcomes are displayed for incident and prevalent patients with or without physician orders for the computer-assisted protocols.
- Mean Hb concentration differences were observed across groups.

Conclusions

- Eighteen months after revision of the FDA label for ESA and the CMS QIP measure for anemia, physicians showed a wide breadth of practice preference for managing ESA dose adjustment.
- At Hb levels above 11.0 g/dL, most physicians preferred to down-titrate rather than hold ESA, but differed on whether to hold at 11.5 g/dL or higher.
- Strong evidence for individualized anemia management was demonstrated by the high proportion of physicians using either no protocol or more than 1 protocol and by the difference in Hb concentrations across groups.
- Eighteen months after the most recent ESA label change, substantial variation in physician practice persisted.
- The 2 trends, individualization of patient care and variation in physician practice preference, each supported availability of multiple anemia protocols.

References

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