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Validation of erythropoietin use data on Medicare's End-Stage Renal Disease Medical Evidence Report

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Abstract—Data from Medicare's End-Stage Renal Disease Medical Evidence Report (Form 2728) suggest that underuse of erythropoiesis-stimulating agents (ESAs) may be contributing to anemia in predialysis patients. However, the data quality of Form 2728 is not known. ESA prescription records were confirmed in Department of Veterans Affairs (VA) data sets and/or ESA claims in Medicare files and compared with data collected on Form 2728 among 8,033 veterans who initiated dialysis in 2000 and 2001 and were eligible for both VA and Medicare coverage in the 12 months preceding dialysis initiation. Among the cohort, predialysis ESA use was found in 4% (n = 323) more veterans by VA/Medicare data sets (n = 2,810) than by Form 2728 (n = 2,487). With the use of VA/Medicare data sets (gold standard), the accuracy of Form 2728 for predialysis ESA use was sensitivity 57.0%, specificity 83.1%, positive predictive value 64.5%, negative predictive value 78.2%, and kappa coefficient 0.41. Sensitivity for reported predialysis ESA use on Form 2728 was lowest among veterans who were female and nonwhite, of low socioeconomic status, and with anemia or other comorbid illnesses. The poor sensitivity and specificity of predialysis ESA use data on Form 2728 raise concerns about the validity of previous reports and study findings. Investigators should recognize these shortcomings and the introduction of possible bias in future research and reports.

Key words: accuracy, elderly, end-stage renal disease, erythropoiesis, Medicare, predialysis, sensitivity, specificity, stimulating agent, validity, veteran.

Abbreviations: CI = confidence interval, CKD = chronic kidney disease, CMS = Centers for Medicare and Medicaid Services, COPD = chronic obstructive pulmonary disease, ESA = erythropoiesis-stimulating agent, ESRD = end-stage renal disease, HSR&D = Health Services Research and Development Service, NPV = negative predictive value, PBM = Pharmacy Benefits Management, PPV = positive predictive value, PSSG = Planning Systems Support Group, RRT = renal replacement therapy, USRDS = United States Renal Data System, VA = Department of Veterans Affairs.

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INTRODUCTION

The incidence and prevalence of end-stage renal disease (ESRD) continue to increase substantially in the United States [1–2]. Prior analyses have found that veterans are at high risk for developing chronic kidney disease (CKD), the precursor to ESRD, and rates of morbidity and mortality are extremely high among veterans with kidney disease [3–5]. At onset of ESRD, the Centers for Medicare and Medicaid Services (CMS) require an ESRD Medical Evidence Report (Form 2728) be completed to certify the patient's need for renal replacement therapy and to signal eligibility for Medicare's ESRD entitlement program. Demographic, medical comorbidity, and laboratory data from Form 2728 have been used for both administrative and research purposes. The United States Renal Data System (USRDS), a comprehensive registry of all patients with ESRD in the United States, publishes annual reports describing the characteristics and clinical attributes of the population with ESRD based on information from Form 2728 [1–2]. CMS dialysis networks across the United States also use data from this source to assess quality of predialysis and dialysis care and to target quality improvement initiatives. Furthermore, researchers have used information from Form 2728 in a large number of clinical, epidemiological, and health services research studies [6–10].

However, we are aware of only one prior study that has attempted to validate any of the Form 2728 information. This study found significant underreporting of major comorbid health conditions compared with reporting of these conditions in patient medical records as a gold standard [11]. This finding raises doubts about the reporting and integrity of other data elements on Form 2728, including the use of erythropoiesis-stimulating agents (ESAs) in patients before attaining ESRD and starting renal replacement therapy (predialysis period). ESAs are recommended and used to correct severe anemia, which occurs frequently as a complication of severe CKD, and may ameliorate many of the negative sequelae of anemia, which include lower quality of life and increased hospitalization, cardiovascular complications, and mortality [12–20]. Recent USRDS reports and clinical studies have suggested that ESA underuse in patients with pre-ESRD may be contributing to the unacceptable severity of anemia in these patients at initiation of dialysis [1–2,6–10,15,19]. To better understand the quality of the data underpinning these observations, we investigated the accuracy and completeness of predialysis ESA use data on Form 2728 by comparing them with Department of Veterans Affairs (VA) pharmacy prescription records and Medicare claims records in a cohort of veterans reliant on VA and/or Medicare-covered services. We also examined whether demographic or clinical factors existed that are associated with the accuracy of the ESA use data.

METHODS

Study Design and Sample

We conducted a retrospective analysis of receipt of ESAs among elderly veterans (aged ≥66 years) who initiated chronic dialysis in 2000 and 2001 and were eligible for both VA and Medicare coverage in the 12 months preceding dialysis initiation. We chose this study population because we were able to confirm their receipt of predialysis ESA using prescription records and claims data, independent of information reported on Form 2728. To identify the study cohort, we used the crosswalk file made available to the VA Information Resource Center [21] from the USRDS, which identifies veterans eligible for VA-covered services who have been registered as patients with ESRD [22]. Veterans eligible for VA-covered services were defined as individuals who used VA healthcare services, were enrolled in the Veterans Health Administration, or received a pension or compensation from the VA. The initiation date of dialysis was identified with the USRDS Patients File [22]. We limited the cohort to veterans initiating chronic dialysis between January 1, 2000, and December 31, 2001, and defined the 12-month period preceding dialysis initiation as the predialysis period.*

We further restricted our sample to veterans who were 66 years old at dialysis initiation to ensure that veterans were also eligible for Medicare-covered services throughout the predialysis period. To ensure adequate capture of healthcare use information including ESA data, we excluded veterans who were enrolled in Medicare but did not have Medicare as their primary payer during this period, were enrolled in a Medicare health-maintenance organization, or had no healthcare use in either the VA or Medicare during the predialysis period [23].

*In this article, we refer to renal replacement therapy (RRT) as dialysis since 99.6% of the study cohort's RRT was chronic dialysis (0.4% underwent kidney transplantation).

ESA Data Collection

VA Data Sets and Medicare Files

ESA use was ascertained from VA pharmacy records (Pharmacy Benefits Management [PBM], Fee Basis) and/or ESA claims under Medicare files (Carrier/Inpatient/Outpatient/durable medical equipment) during the 12-month predialysis period. PBM data capture medications dispensed from VA pharmacies. A dispensation of "erythropoietin" or "darbepoietin" in such data was consistent with receipt of ESA in the VA. Any occurrence of current procedural terminology codes for ESAs in Medicare claims data was deemed consistent with receipt of ESA under Medicare.

Form 2728

The CMS ESRD Medical Evidence Report, from here on known as Form 2728, is required for all patients reaching ESRD requiring RRT and becoming eligible for Medicare's ESRD program. On the front page of Form 2728 (version 6-97), question 17 states, "Was predialysis/transplant EPO [erythropoietin] administered?" Possible responses include "yes" or "no." A "yes" response was considered to indicate ESA was administered in the predialysis period, while a "no" response was considered to indicate ESA was not administered in the predialysis period. Nonresponses were considered to indicate that ESA was not administered but were also excluded and examined in a sensitivity analysis.

Variables

We obtained data on veteran characteristics from VA Inpatient and Outpatient Medical SAS [SAS Institute Inc, Cary, North Carolina] data sets, the Medicare Denominator file, and the USRDS Patients File and Form 2728 [22,24–25]. Comorbidities were assigned on the basis of diagnostic and procedure codes in the inpatient and outpatient VA data sets and Medicare claims data [26]. Anemia was defined as serum hemoglobin <10 g/dL, as reported in Form 2728, and supplemented with the VA Decision Support System Laboratory Results file [27]. VA priority level was defined as "high" for veterans with a service-connected condition or whose income was less than a VA-established annual threshold (VA priority groups 1–6), "low" for those whose income was greater than the annual income threshold, and "missing" for veterans with no designation available [28]. To account for socioeconomic status, we linked information about the patients' ZIP Code of residence obtained from the VA Planning Systems Support Group (PSSG) with information from the 2000 Census [29], including ZIP Code-based median household income, education levels, and county unemployment rate from the Area Resource File [30–31]. In addition to including veteran census region, the urban/rural nature of a ZIP Code was obtained from the VA PSSG [29].

We also classified veterans by the healthcare system(s) in which they received outpatient healthcare during the predialysis period: (1) VA outpatient care only (VA-only), (2) VA and Medicare outpatient care (dual), and (3) Medicare outpatient care only (Medicare-only). Adapting a previously developed algorithm [32], we determined the healthcare system from VA and/or Medicare encounters in the following types of outpatient care: primary, specialty, auxiliary clinic, and psychiatric. Any single VA or Medicare encounter for any of these four groups was considered evidence of healthcare use in that particular system. We identified episodes of outpatient nephrology care during the 12-month predialysis period using both VA outpatient administrative data and Medicare carrier files. Nephrology care was defined as the presence of any of the following during the predialysis period: nephrology clinic visit (VA), outpatient hypertension clinic visit with a nephrology provider (VA), and nephrology provider visit (Medicare). Because visits coded as level 1 in Medicare do not require interaction with a nephrology practitioner, these visits were excluded.

Statistical Methods

Using previously published methods [11,33–34], we categorized veterans according to predialysis ESA use reported on Form 2728 in relation to ESA prescription records in VA data sets and ESA claims in Medicare files during the 12-month predialysis period (**Table 1**).

Using the number of veterans in each group (**Table 1**), we computed four comparison statistics using VA data sets and/or Medicare files as the gold standard:

- A = true positive.
- B = false positive.
- C = false negative.
- D = true negative.

Sensitivity indicates the percentage of subjects *with* predialysis ESA use that was correctly recorded on Form 2728 and was computed as the ratio of true positives to true positives plus false negatives (A/(A + C)). Specificity refers to the percentage of subjects *without* predialysis ESA use that was correctly recorded on

Table 1.
Definitions of four groups for assessing accuracy of erythropoiesis-stimulating agent (ESA) data in Medicare's End-Stage Renal Disease Medical Evidence Report.

Group	Definition
A. True Positive	Veterans received predialysis ESAs on Form 2728. A prescription for ESAs was present in VA/Medicare data sets.
B. False Positive	Veterans received predialysis ESAs on Form 2728. A prescription for ESAs was not present in VA/Medicare data sets.
C. False Negative	Veterans did not receive predialysis ESAs on Form 2728. A prescription for ESAs was present in VA/Medicare data sets.
D. True Negative	Veterans did not receive predialysis ESAs on Form 2728. A prescription for ESAs was not present in VA/Medicare data sets.

VA = Department of Veterans Affairs.

Form 2728 and computed as the ratio of true negatives to true negatives plus false positives (D/(D + B)). Positive predictive value (PPV) refers to the percentage of subjects that was identified as having predialysis ESA use on Form 2728 and actually had such use and was computed as the ratio of true positives to true positives plus false positives (A/(A + B)). Negative predictive value (NPV) refers to the percentage of subjects that was identified as *not* having predialysis ESA use on Form 2728 and did not have such use and was computed as the ratio of true negatives to true negatives plus false negatives (D/(D + C)). As a measure of agreement between Form 2728 and VA data sets and/or Medicare files regarding predialysis ESA use data, a κ coefficient was calculated as (observed agreement – chance agreement)/(1 – chance agreement), where observed agreement = A + D/(A + B + C + D) and chance agreement = (C + D)/(A + B + C + D) × (B + D)/(A + B + C + D) + (A + C)/(A + B + C + D) × (A + B)/(A + B + C + D).

We computed sensitivity, specificity, PPV, NPV, and κ coefficient for the overall cohort, demographic subgroups of the cohort, and outpatient care subgroups of the cohort. All analyses were conducted with the use of STATA SE version 9.03 (StataCorpLP; College Station, Texas).

RESULTS

Participants

The final analytic cohort comprised 8,033 veterans after excluding 4,453 veterans: 2,453 who did not receive outpatient care from either the VA or Medicare during the predialysis period, 1,318 who were enrolled in Medicare managed care plans, and 682 who did not have Medicare as their primary payer. Of the veterans, 17 percent were VA-only (n = 1,395), 44 percent were dual (n = 3,545), and 39 percent were Medicare-only (n = 3,093) outpatient care users. Sixty-three percent of veterans received predialysis nephrology care (n = 5,059), while thirty-seven percent did not (n = 2,974).

Descriptive Data

More than 80 percent of the cohort were elderly non-Hispanic white veterans (**Table 2**). More than 50 percent of the study veterans had diabetes mellitus, hypertension, or congestive heart failure, while approximately 23 percent or more had peripheral vascular disease, coronary artery disease, or chronic obstructive pulmonary disease (COPD). Approximately 45 percent of the cohort had either Medicaid or no additional health insurance beyond VA and Medicare coverage. Nearly 1 in 5 veterans resided in counties or ZIP Codes with low median household income, a low percentage of college graduates, or high unemployment. Over 80 percent of veterans lived in urban ZIP Codes from all regions of the United States.

Accuracy of ESA Data on Form 2728

Overall

Among 8,033 veterans in the final cohort (**Table 3**), predialysis ESA use was found in 4 percent (n = 323) more veterans by VA/Medicare data sets (n = 2,810) than by Form 2728 (n = 2,487). The overall accuracy of Form 2728 for predialysis ESA use was low: sensitivity 57.0 percent, specificity 83.1 percent, PPV 64.5 percent, and NPV 78.2 percent. Agreement between the two data sources was also fair with a κ coefficient in abstract and of 0.41. A sensitivity analysis was also performed, excluding those subjects with missing responses for predialysis ESA on Form 2728 (n = 196), and the results were not significantly different.

Table 2.
Characteristics of veterans (N = 8,033).

Characteristic	Overall % (n)
Age (yr)	
≥66 to 74	38.6 (3,104)
>74	61.4 (4,929)
Sex	
Male	97.5 (7,831)
Female	2.5 (202)
Race	
White	81.2 (6,521)
African American	16.4 (1,314)
Other	2.4 (198)
Hispanic	
Yes	5.8 (470)
No	94.2 (7,563)
Body Mass Index (kg)	
≥30	17.0 (1,363)
<30	83.0 (6,670)
Comorbidities	
Diabetes Mellitus	55.0 (4,417)
Hypertension	89.9 (7,220)
Peripheral Vascular Disease	25.4 (2,041)
Coronary Artery Disease	23.2 (1,862)
Congestive Heart Failure	56.6 (4,546)
Stroke	15.6 (1,253)
COPD	32.8 (2,633)
Anemia	44.7 (3,594)
Additional Insurance	
None	34.3 (2,753)
Medicaid	10.6 (850)
Private	55.1 (4,430)
VA Priority Level	
High	66.0 (5,298)
Low	20.6 (1,656)
Missing	13.4 (1,079)
Median Household Income by ZIP Code ($U.S.)*	
<30,000	22.2 (1,785)
≥30,000	77.8 (6,248)
College Graduate by ZIP Code (%)	
<10	15.9 (1,280)
≥10	84.1 (6,753)
Unemployment by ZIP Code by County (%)	
>6	19.0 (1,525)
≤6	81.0 (6,508)
Type of ZIP Code	
Urban	81.3 (6,530)
Rural	18.7 (1,503)
Region	
Northeast	19.7 (1,581)
Midwest	26.2 (2,106)
South	38.9 (3,128)
West	13.5 (1,081)
Territory	1.7 (137)

*In thousands of dollars, rounded to nearest hundredth dollar.
COPD = chronic obstructive pulmonary disease, VA = Department of Veterans Affairs.

By Anemia

Sensitivity of predialysis ESA use on Form 2728 was lower among veterans with anemia (hemoglobin <10 g/dL) at onset of ESRD than those without anemia (52.6% vs 62.1%), while smaller differences existed in other comparison statistics (**Table 4**). Overall agreement by κ coefficient was 0.38 for veterans with anemia compared with 0.44 for veterans without anemia.

By Demographic and Clinical Subgroups

Differences in comparison statistics existed across multiple demographic and clinical subgroups, especially regarding sensitivity (**Table 5**). Sensitivity of Form 2728 predialysis ESA use was lower in female (51.4%, 95% confidence interval [CI]: 39.2–63.6) compared with male veterans (57.2%, 95% CI: 55.3–59.1) as well as African-American veterans (53.3%, 95% CI: 48.7–57.7) compared with their white counterparts (58.0%, 95% CI: 55.9–60.0). Several other socioeconomic factors were associated with lower sensitivity of predialysis ESA use on Form 2728, including Medicaid insurance (48.6%), low median household income (53.4%), low proportion of college graduates (54.2%), and high unemployment (53.5%). Compared with those without comorbidities, veterans with comorbid conditions such as diabetes, vascular disease, and COPD tended to have a lower sensitivity for reported predialysis ESA use on Form 2728.

By Outpatient Care Subgroups

Compared with veterans who received outpatient predialysis nephrology care, veterans who did not had a lower sensitivity and κ coefficient on Form 2728 for reported predialysis ESA use, 48.1 versus 58.9 percent and 0.31 versus 0.40, respectively (**Table 6**). Smaller differences existed in sensitivity among VA-only, dual, and Medicare-only outpatient care users.

DISCUSSION

To our knowledge, this analysis is the first detailed examination of the accuracy of predialysis ESA data reported on Medicare's Form 2728. We found significant misclassification of predialysis ESA data on Form 2728 in veterans incident to ESRD who required dialysis, with an overall sensitivity of 57.0 percent and specificity of 83.1 percent. Inaccuracy of ESA reporting on Form 2728 yielded prevalence estimates of ESA use that were 4 percent lower

Table 3.
Overall accuracy of erythropoiesis-stimulating agent (ESA) data in Medicare's End-Stage Renal Disease Medical Evidence Report (Form 2728) of veterans (N = 8,033).

Predialysis ESA in Form 2728	Predialysis ESA in VA/Medicare Data Sets		Sensitivity* (%)	Specificity† (%)	PPV‡ (%)	NPV§ (%)	κ
	Yes	No	(95% Confidence Interval)				
Yes	1,603	884	57.0	83.1	64.5	78.2	0.41
No¶	1,207	4,339	(55.2–58.9)	(82.0–84.1)	(62.5–66.3)	(77.1–79.3)	(0.39–0.43)

*Sensitivity = true positives/(true positives + false negatives) × 100.
†Specificity = true negatives/(true negatives + false positives) × 100.
‡PPV = true positives/(true positives + false positives) × 100.
§NPV = true negatives/(true negatives + false negatives) × 100.
¶196 of 8,033 (2.4%) were missing predialysis ESA information on Form 2728 and were considered consistent with no predialysis ESA.
NPV = negative predictive value, PPV = positive predictive value, VA = Department of Veterans Affairs.

Table 4.
Accuracy of erythropoiesis-stimulating agent (ESA) data in Medicare's End-Stage Renal Disease Medical Evidence Report (Form 2728) by presence of anemia.

Predialysis ESA in Form 2728	Predialysis ESA in VA/Medicare Data Sets		Sensitivity* (%)	Specificity† (%)	PPV‡ (%)	NPV§ (%)	κ
	Yes	No	(95% Confidence Interval)				
No Anemia Present							
Yes	914	467	62.1	81.3	66.2	78.5	0.44
No	558	2,033	(59.6–64.6)	(79.7–82.8)	(63.6–68.7)	(76.8–80.0)	(0.41–0.47)
Anemia Present							
Yes	646	381	52.6	83.9	62.9	77.3	0.38
No	583	1,984	(49.7–55.4)	(82.3–85.4)	(59.9–65.9)	(75.6–78.9)	(0.35–0.41)
Anemia Not Assessed							
Yes	43	36	39.4	89.9	54.4	83	0.32
No	66	322	(30.2–49.3)	(86.4–92.9)	(42.8–65.7)	(78.9–86.6)	(0.22–0.43)

*Sensitivity = true positives/(true positives + false negatives) × 100.
†Specificity = true negatives/(true negatives + false positives) × 100.
‡PPV = true positives/(true positives + false positives) × 100.
§NPV = true negatives/(true negatives + false negatives) × 100.
NPV = negative predictive value, PPV = positive predictive value, VA = Department of Veterans Affairs.

than those based on documented ESA use in the VA and/or Medicare. Sensitivity was poor (ranging from 48.6% to 65.3%), and specificity (ranging from 77.1% to 86.3%) was moderate for all groups. Sensitivity was worse in veterans who were female, nonwhite, those of low socioeconomic status, and those with a greater burden of comorbid illness. Only one prior study commented on predialysis ESA data on Form 2728 [35]. In a retrospective cohort analysis of elderly (aged >66 years) Medicare recipients incident to hemodialysis from 1995 to 1997, Xue et al. briefly noted that although nearly 24 percent of study participants were reported to receive an ESA before starting dialysis on Form 2728, only 15.6 percent received an ESA before ESRD according to their review of Medicare claims data [35]. Although Medicare was the primary payer for subjects in this study, the authors acknowledged that other payers could be covering ESAs for these Medicare patients and hence explain the higher ESA use reported by Form 2728 versus that found in Medicare claims; however, comparative statistics were not reported. In contrast, our study population was required not only to be Medicare-eligible and to have Medicare as a primary payer but also to be eligible for VA-covered services, thereby diminishing the risk that ESA could have been provided outside of Medicare or VA. Furthermore, we did not find the accuracy of Form 2728 to be worse in veterans who had additional private insurance versus those without additional insurance.

In their evaluation of the accuracy of comorbid conditions on Form 2728, Longenecker et al. noted an overall sensitivity of 59 percent and specificity of 91 percent,

Table 5.
Accuracy of erythropoiesis-stimulating agent (ESA) data in Medicare's End-Stage Renal Disease Medical Evidence Report (Form 2728) by demographic and clinical subgroups.

Characteristic	Sensitivity (%)*	Specificity (%)†	PPV (%)‡	NPV(%)§	κ
	(95% Confidence Interval)				
Age (yr)					
≥66 to 74	58.0 (55.0–61.0)	83.3 (81.5–84.9)	65.1 (62.0–68.1)	78.7 (76.9–80.4)	0.42 (0.39–0.46)
>74	56.4 (54.1–58.8)	83.0 (81.6–84.3)	64.1 (61.6–66.5)	78.0 (76.5–79.4)	0.40 (0.38–0.43)
Sex					
Male	57.2 (55.3–59.1)	83.2 (82.1–84.2)	64.6 (62.7–66.6)	78.3 (77.2–79.4)	0.41 (0.39–0.44)
Female	51.4 (39.2–63.6)	79.5 (71.7–86.1)	57.1 (44.0–69.5)	75.5 (67.5–82.4)	0.32 (0.18–0.45)
Race					
White	58.0 (55.9–60.0)	83.3 (82.2–84.4)	64.8 (62.7–66.9)	78.9 (77.7–80.1)	0.42 (0.40–0.45)
African American	53.3 (48.7–57.7)	82.8 (80.1–85.4)	65.0 (60.1–69.7)	74.8 (71.8–77.5)	0.37 (0.32–0.43)
Other	53.4 (39.9–66.7)	77.1 (69.3–83.8)	49.2 (36.4–62.1)	80.0 (72.3–86.4)	0.30 (0.16–0.44)
Hispanic					
Yes	59.5 (51.4–67.2)	83.7 (79.1–87.6)	64.8 (56.5–72.6)	80.3 (75.6–84.5)	0.44 (0.35–0.53)
No	56.9 (55.0–58.8)	83.0 (82.0–84.1)	64.4 (62.5–66.4)	78.1 (77.0–79.2)	0.41 (0.39–0.43)
BMI (kg)					
≥30	58.8 (54.2–63.4)	86.2 (83.8–88.3)	67.9 (63.0–72.5)	80.8 (78.2–83.3)	0.47 (0.41–0.52)
<30	56.7 (54.7–58.7)	82.4 (81.3–83.5)	63.8 (61.7–65.9)	77.7 (76.4–78.9)	0.40 (0.38–0.42)
Comorbidities					
Diabetes Mellitus					
Yes	55.2 (52.8–57.7)	83.0 (81.5–84.4)	65.6 (63.0–68.1)	76.0 (74.4–77.5)	0.39 (0.37–0.42)
No	59.6 (56.7–62.4)	83.2 (81.6–84.7)	63.1 (60.2–65.9)	81.0 (79.4–82.5)	0.43 (0.40–0.46)
Hypertension					
Yes	57.0 (55.1–58.9)	82.7 (81.6–83.8)	65.6 (63.6–67.5)	76.9 (75.7–78.1)	0.41 (0.39–0.43)
No	57.5 (49.6–65.1)	85.8 (82.8–88.4)	51.1 (43.7–58.4)	88.6 (85.9–91.0)	0.41 (0.34–0.49)
Peripheral Vascular Disease					
Yes	54.9 (51.1–58.8)	84.0 (82.0–85.9)	62.0 (57.9–66.0)	79.7 (77.6–81.7)	0.40 (0.36–0.44)
No	57.7 (55.6–59.8)	82.7 (81.5–83.9)	65.2 (63.0–67.3)	77.7 (76.4–79.0)	0.41 (0.39–0.44)
Coronary Artery Disease					
Yes	52.6 (48.4–56.7)	85.6 (83.5–87.4)	61.4 (56.9–65.8)	80.5 (78.3–82.5)	0.40 (0.35–0.44)
No	58.2 (56.1–60.2)	82.3 (81.0–83.4)	65.2 (63.1–67.3)	77.5 (76.2–78.8)	0.41 (0.39–0.44)
Congestive Heart Failure					
Yes	52.6 (50.0–55.1)	83.6 (82.2–84.9)	60.9 (58.2–63.6)	78.4 (76.9–79.8)	0.37 (0.35–0.40)
No	62.1 (59.4–64.7)	82.4 (80.7–84.0)	68.3 (65.6–70.9)	78.1 (76.3–79.7)	0.45 (0.42–0.48)
Stroke					
Yes	53.9 (48.8–59.0)	84.2 (81.6–86.6)	59.8 (54.4–65.0)	80.8 (78.1–83.3)	0.39 (0.34–0.45)
No	57.5 (55.5–59.5)	82.9 (81.7–84.0)	65.2 (63.1–67.2)	77.7 (76.5–78.9)	0.41 (0.39–0.44)
COPD					
Yes	50.9 (47.4–54.5)	84.6 (82.9–86.2)	58.9 (55.1–62.6)	79.9 (78.1–81.7)	0.37 (0.33–0.41)
No	59.5 (57.3–61.6)	82.3 (80.9–83.5)	66.6 (64.4–68.8)	77.3 (75.9–78.7)	0.43 (0.40–0.45)
Additional Insurance					
None	56.7 (53.6–59.8)	86.3 (84.6–87.9)	70.3 (67.0–73.4)	77.7 (75.8–79.6)	0.45 (0.41–0.48)
Medicaid	48.6 (42.1–55.0)	83.2 (80.0–86.1)	53.6 (46.8–60.4)	80.2 (76.8–83.2)	0.33 (0.26–0.40)
Private	58.6 (56.1–61.0)	81.1 (79.6–82.5)	62.9 (60.3–65.3)	78.2 (76.6–79.6)	0.40 (0.37–0.43)
VA Priority Level					
High	56.2 (53.9–58.4)	84.0 (82.7–85.2)	65.6 (63.2–67.9)	77.9 (76.6–79.3)	0.41 (0.39–0.44)
Low	62.3 (58.4–66.1)	81.4 (78.8–83.7)	66.7 (62.7–70.6)	78.3 (75.7–80.7)	0.44 (0.40–0.49)
Missing	52.0 (46.4–57.5)	81.2 (78.2–83.9)	54.3 (48.6–60.0)	79.7 (76.7–82.5)	0.34 (0.27–0.40)

Table 5. (Continued)
Accuracy of erythropoiesis-stimulating agent (ESA) data in Medicare's End-Stage Renal Disease Medical Evidence Report (Form 2728) by demographic and clinical subgroups.

Characteristic	Sensitivity (%)*	Specificity (%)†	PPV (%)‡	NPV(%)§	κ
	(95% Confidence Interval)				
Median Household Income by ZIP Code ($U.S.)¶					
<30,000	53.4 (49.1–57.7)	84.1 (82.0–86.1)	59.5 (55.0–63.9)	80.5 (78.2–82.6)	0.39 (0.34–0.43)
≥30,000	57.9 (55.9–60.0)	82.7 (81.5–83.9)	65.6 (63.5–67.7)	77.5 (76.3–78.8)	0.42 (0.39–0.44)
College Graduate by ZIP Code (%)					
<10	54.2 (49.1–59.2)	82.3 (79.6–84.7)	57.7 (52.5–62.8)	80.1 (77.3–82.6)	0.37 (0.32–0.43)
≥10	57.5 (55.5–59.5)	83.2 (82.1–84.3)	65.6 (63.6–67.7)	77.9 (76.7–79.1)	0.42 (0.40–0.44)
Unemployment by ZIP Code by County (%)					
>6	53.5 (48.9–58.1)	84.8 (82.5–87.0)	61.1 (56.2–65.8)	80.4 (78.0–82.7)	0.40 (0.35–0.45)
≤6	57.8 (55.7–59.8)	82.6 (81.4–83.8)	65.1 (63.0–67.2)	77.7 (76.4–78.9)	0.41 (0.39–0.44)
Type of ZIP Code					
Urban	56.6 (54.6–58.6)	83.1 (81.9–84.2)	65.3 (63.1–67.3)	77.3 (76.0–78.5)	0.41 (0.38–0.43)
Rural	59.3 (54.7–63.9)	83.1 (80.7–85.4)	60.8 (56.1–65.3)	82.3 (79.8–84.5)	0.43 (0.38–0.48)
Region					
Northeast	58.6 (54.6–62.6)	78.8 (76.1–81.3)	63.4 (59.3–67.4)	75.2 (72.5–77.9)	0.38 (0.33–0.43)
Midwest	57.6 (53.7–61.4)	83.9 (81.9–85.7)	62.3 (58.4–66.2)	81.0 (78.9–83.0)	0.42 (0.38–0.46)
South	55.2 (52.2–58.2)	85.1 (83.4–86.6)	66.9 (63.7–69.9)	77.7 (75.9–79.4)	0.42 (0.39–0.45)
West	57.9 (52.8–62.9)	81.3 (78.2–84.1)	62.7 (57.4–67.8)	78.1 (74.9–81.0)	0.40 (0.34–0.46)
Territory	65.3 (50.4–78.3)	85.2 (76.1–91.9)	71.1 (55.7–83.6)	81.5 (72.1–88.9)	0.51 (0.36–0.67)

*Sensitivity = true positives/(true positives + false negatives) × 100.
†Specificity = true negatives/(true negatives + false positives) × 100.
‡PPV = true positives/(true positives + false positives) × 100.
§NPV = true negatives/(true negatives + false negatives) × 100.
¶In thousands of dollars, rounded to nearest hundredth dollar.
BMI = body mass index, COPD = chronic obstructive pulmonary disease, NPV = negative predictive value, PPV = positive predictive value, VA = Department of Veterans Affairs.

which were consistent with the degree of under- and overreporting of predialysis ESA in our study [11]. They also noted worse sensitivity in females, African Americans, and those with multiple comorbid conditions. Noteworthy is that the presence of comorbid conditions and use of predialysis ESA on Form 2728 simply require the respondent to mark an appropriate box. The respondent receives no specific training for completing Form 2728. Moreover, tremendous heterogeneity exists in the identity of the respondent because it may be any one or a combination of individuals, including the patient, social worker, nurse, administrator, or nephrologist. In this setting, interpretation and understanding of questions such as "Was predialysis/transplant EPO administered?" and the gathering of patient information to answer such questions in an informed manner are highly variable. In vulnerable populations, such as those characterized by complex comorbid conditions, low socioeconomic status, minority race, and absent predialysis nephrology care, accurate completion of Form 2728 is likely further compromised by issues of patient health literacy, patient education and awareness about CKD and its treatment, and provider-patient communication.

Similar to the implications cited by Longenecker et al., two types of biases may result from the use of Form 2728 predialysis ESA data for administrative and research purposes: (1) underreporting bias of predialysis ESA and (2) differential bias regarding the association of certain characteristics with predialysis ESA [11]. Multiple USRDS reports using Form 2728 data have concluded that ongoing levels of suboptimal degrees of anemia in incident patients with ESRD are in part because of underuse of ESA [17]. These reports have consistently cited lower hemoglobin values in patients without ESA use compared with those with ESA use and have suggested that more appropriate use of predialysis ESA is an important target of quality improvement in patient care. Moreover, recent large observational studies and clinical

Table 6.
Accuracy of erythropoiesis-stimulating agent (ESA) data in Medicare's End-Stage Renal Disease Medical Evidence Report (Form 2728) by outpatient care subgroups.

Type of Outpatient Predialysis Care	Sensitivity (%)*	Specificity (%)†	PPV (%)‡	NPV (%)§	κ
	(95% Confidence Interval)				
Predialysis Nephrology Care					
Yes	58.9 (56.9–60.9)	80.8 (79.3–82.3)	72.3 (70.3–74.4)	69.8 (68.1–71.4)	0.40 (0.38–0.43)
No	48.1 (43.6–52.7)	85.6 (84.1–86.9)	39.2 (35.2–43.3)	89.5 (88.2–90.7)	0.31 (0.27–0.35)
Outpatient Care					
VA-Only	58.4 (54.1–62.6)	86.5 (84.0–88.7)	73.4 (68.9–77.5)	76.5 (73.7–79.2)	0.47 (0.42–0.51)
Dual	55.5 (52.8–58.2)	83.9 (82.3–85.4)	67.6 (64.8–70.4)	75.7 (74.0–77.4)	0.41 (0.38–0.44)
Medicare-Only	58.4 (55.2–61.6)	80.9 (79.1–82.5)	56.8 (53.6–59.9)	81.9 (80.2–83.5)	0.39 (0.35–0.42)

*Sensitivity = true positives/(true positives + false negatives) × 100.
†Specificity = true negatives/(true negatives + false positives) × 100.
‡PPV = true positives/(true positives + false positives) × 100.
§NPV = true negatives/(true negatives + false negatives) × 100.
NPV = negative predictive values, PPV - positive predictive values, VA = Department of Veterans Affairs.

review articles, which relied on Form 2728 data, have also found that less than one-third of patients with incident dialysis received predialysis ESA and that those with lower hemoglobin values were even less likely to have received predialysis ESA [6–10,15–16,19]. Only one group of investigators expressed concern about predialysis ESA data misclassification on Form 2728, but doubted it was significant because an inverse correlation was found between ESA use and low hemoglobin ($r = -0.65$, $p = 0.004$) [6,8]. Our detailed analysis of Form 2728 predialysis ESA data suggests otherwise. While our findings do not entirely discount the observed relationship between lack of ESA use and worse anemia, they do suggest that it has been exaggerated. Especially considering that sensitivity and underreporting were observed as worse in those with anemia compared with those without anemia, these results require a reexamination of this matter and greater attention to other important factors affecting anemia management in patients with pre-ESRD, such as dosing of ESA and iron therapy.

Differential bias is also a potential consequence of using predialysis ESA data on Form 2728. USRDS annual reports have found that African Americans had worse anemia parameters at initiation of dialysis and were less likely to receive ESA than whites [1–2]. Based on Form 2728 data, several epidemiological studies over the past decade have contended that the African-American race, unemployment, and Medicaid insurance are independently associated with a lower likelihood of predialysis ESA [6–10,36]. While these disparities may exist and be influenced by economic and healthcare access as these investigators contend, our findings suggest that some of these associations may be the result of bias because of poor sensitivity and misclassification of data on Form 2728 in these groups. These potentially erroneous relationships could obfuscate the determination of appropriate subgroups for targeting improvements in pre-ESRD anemia care.

In 2005, a new Form 2728 was adopted and disseminated that contains new information regarding prior ESA therapy in patients with incident ESRD. The question has been restated as "Prior to ESRD therapy, did patient receive exogenous erythropoietin or equivalent?" and the options for responses include "yes," "no," or "unknown." If "yes" is indicated, then the respondent is further asked if such therapy was given for "6 to 12 months" or ">12 months." This new language and "unknown" response option may enhance the accuracy of Form 2728 ESA data by reducing misunderstanding of the question and allowing for an appropriate choice if the receipt of predialysis ESA is uncertain. Furthermore, the additional specific data requested may improve characterization of predialysis ESA use across the United States. Evaluation of the data quality of this revised Form 2728 is needed to inform administrators and investigators how best to use this information to assess quality of pre-ESRD care and epidemiological research endeavors. In the interim, while the use of predialysis ESA data on Form 2728 offers many advantages, including being inexpensive to use, being readily available, and characterizing a large national patient sample, the data's use is compromised by data misclassification and poor sensitivity. These shortcomings

and biases should be kept in mind when results are reported and interpreted based on these data.

This study has limitations. First, this study was conducted in a predominantly older male population. Therefore, findings for the accuracy of predialysis ESA data on Form 2728 may not be generalizable to other demographic groups. Second, despite the careful efforts to restrict the cohort to veterans reliant only on the VA and Medicare, predialysis ESA may possibly have been obtained outside of the VA or Medicare, especially in veterans with private insurance or Medicaid. This phenomenon would lower specificity in these analyses because it would inflate the degree of false positives. However, sensitivity was lower than specificity in our analysis and the latter did not vary substantially across key subgroups. Also, PBM data during this time period only captured outpatient ESA use; therefore, ESA use during a VA hospitalization may not be captured by our analysis. In addition, we underscore the importance that ESA use for anemia due to CKD is a chronic therapy that would be unlikely to occur solely during an inpatient period; therefore, this underestimating of VA ESA use is likely not significant. Furthermore, we did not find substantial differences in sensitivity and specificity among veterans whose ESA use was confirmed exclusively in PBM records (i.e., VA-only users) versus exclusively in Medicare claims data (i.e., Medicare-only users). Hence, our findings appear quite robust.

CONCLUSIONS

Reporting of predialysis ESA use on Form 2728 suffers significant errors in underreporting and overreporting. Investigators should recognize these shortcomings and the introduction of possible bias in prior and future research and national reports. Nonetheless, administrative data remain a readily available and important repository of information for medical research. As has been suggested in the past [37], efforts and coordination among clinicians, researchers, and policy makers are greatly needed to further develop linked electronic medical records and databases to improve the quality of administrative data sources such as Form 2728.

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