

DRAFT

Anemia of chronic kidney disease: Hemoglobin < 10 g/dL

3b Measure Justification

Importance

- ◆ **High Impact Aspect of Health Care**
 - **Demonstrated high impact aspect**

1a1.1 Select from the following all that apply:

- Affects large numbers
- A leading cause of morbidity/mortality
- Frequently performed procedure
- High resource use
- Patient/societal consequences of poor quality

Erythropoiesis-stimulating agents (ESAs) are indicated for the treatment of anemia in patients with Chronic Kidney Disease (CKD). Changes in financial incentives for providing ESAs for treatment of anemia following the implementation of the prospective payment system and changes in the FDA recommendations on ESA use, have given rise to concerns that patients with low hemoglobin (Hgb) may be denied access to ESAs in favor of red blood cell transfusion. In addition, treatment of severe anemia is believed by many in the renal community to improve patient reported quality of life (QoL). The Food & Drug Administration (FDA) recommends that lowest level of ESA should be used in order to avoid transfusions and that ESA therapy be initiated when Hgb levels are below 10 g/dl. In addition, the FDA recommends that ESA therapy be individualized to the patient as some patients may be willing to accept increased cardiovascular risk with ESA treatment for potential improvements in QoL (e.g. fatigue, physical function, exercise capacity). Patients with a recent diagnosis of cancer were excluded because of safety concerns related to ESA use in patients with active malignancy, reflected in both the FDA recommendations and KDIGO clinical practice guidelines.

- **Summary of evidence of high impact**

1a3. Provide epidemiological or resource use data

A systematic review involving dialysis patients and QoL shows that QoL is possibly maximized with a Hgb range of 10-12 g/dl. The systematic review was based on physical function and exercise tolerance in dialysis patients.

KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease

- 3.4.3: For adult CKD 5D patients, we suggest that ESA therapy be used to avoid having the Hgb concentration fall below 9.0 g/dl (90 g/l) by starting ESA therapy when the hemoglobin is between 9.0–10.0 g/dl (90–100 g/l).
- 3.4.4: Individualization of therapy is reasonable as some patients may have improvements in quality of life at higher Hb concentration and ESA therapy may be started above 10.0 g/dl (100 g/l). (Not Graded)

KDIGO Anemia Guidelines 2012: Guideline 4.1.3: When managing chronic anemia, we suggest that the benefits of red cell transfusions may outweigh the risks in patients in whom (2C):

- ESA therapy is ineffective (e.g., hemoglobinopathies, bone marrow failure, ESA resistance)
- The risks of ESA therapy may outweigh its benefits (e.g., previous or current malignancy, previous stroke)

KHA-CARI Guideline

- Suggest that in dialysis patients with anaemia due to CKD, an erythropoiesis-stimulating agent (ESA) can be used to prevent the haemoglobin falling below 95 g/L in order to avoid the need for blood transfusion and to improve quality of life.

NICE UK Anaemia Management in Chronic Kidney Disease Guidelines

- Typically maintain the aspirational Hb range between 10 and 12 g/dl for adults, young people and children aged 2 years and older, and between 9.5 and 11.5 g/dl for children younger than 2 years of age, reflecting the lower normal range in that age group.
- To keep the Hb level within the aspirational range, do not wait until Hb levels are outside the aspirational range before adjusting treatment (for example, take action when Hb levels are within 0.5 g/dl of the range's limits). [NICE 2011]
- Consider investigating and managing anaemia in people with CKD if:
 - their Hb level falls to 11 g/dl or less (or 10.5 g/dl or less if younger than 2 years) or,
 - they develop symptoms attributable to anaemia (such as tiredness, shortness of breath, lethargy and palpitations). [NICE 2011]

○ Citations

1a.4. Provide citations for the evidence described above

FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease.

<http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm>

2012 Anemia Management TEP Summary Report

http://www.dialysisreports.org/pdf/esrd/public-measures/Final_TEP_Summary_Report_10252012_508.pdf

KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease

http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf

KHA-CARI guideline

McMahon LP and MacGinley R. KHA-CARI guideline: Biochemical and haematological targets: Haemoglobin concentrations in patients using erythropoietin-stimulating agents. *Nephrology* 2012;17(1):17-9.

KDOQI Guidelines

KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. *Am J Kidney Dis* 2007 50(3):471-530.

NICE 2011: UK Anaemia Management in Chronic Kidney Disease Guidelines, No. 114 National Clinical Guideline Centre (UK). London: Royal College of Physicians (UK); February 2011.
<http://www.ncbi.nlm.nih.gov/books/NBK65530/>

Johansen KL, Finkelstein FO, Revicki DA et al. Systematic review and meta-analysis of exercise tolerance and physical functioning in dialysis patients treated with erythropoiesis-stimulating agents. *Am J Kidney Dis* 2010; 55: 535–548

◆ **Opportunity for Improvement**

○ **Briefly explain the benefits envisioned by use of this measure**

1b.1. (Quality improvement anticipated)

This measure is intended to guard against decline in access to optimal care for dialysis patients by monitoring achieved Hgb values that are used to determine ESA dosing and need for transfusions. Changes in economic incentives of EPO dose and well documented guidelines about risks associated with excessive ESA dose may result in lower achieved Hgb values that may have an adverse impact on QoL. This measure is intended to guard against underuse of ESAs.

○ **Summary of data demonstrating performance gap**

1b.2. (Variation or overall less than optimal performance across providers)

In the test calculation of the measure using the 1st quarter of 2011 Medicare claims data, the facility-level mean was 7.1% (SD 8.5%) with the 25th percentile, median and 75th percentile being 1.7%, 5.4% and 9.7%, respectively.

Year/Quarter	Number of Facilities	Mean % Hgb < 10	Std Dev	25th Pctl	Median	75th Pctl
2008 Q1	4842	4.2%	6.9%	0.0%	2.7%	5.7%
2008 Q2	4883	4.5%	7.4%	0.0%	2.8%	6.2%
2008 Q3	4943	4.1%	6.2%	0.0%	2.8%	5.9%
2008 Q4	4993	4.5%	6.9%	0.0%	3.2%	6.3%
2009 Q1	5117	4.9%	7.7%	0.0%	3.4%	6.7%
2009 Q2	5164	5.0%	6.9%	0.0%	3.6%	7.1%
2009 Q3	5219	5.2%	7.5%	0.0%	3.6%	7.1%
2009 Q4	5263	5.2%	7.3%	0.0%	3.7%	7.2%
2010 Q1	5318	5.3%	7.0%	0.0%	3.8%	7.4%
2010 Q2	5363	5.4%	7.1%	0.0%	3.9%	7.5%
2010 Q3	5411	5.9%	8.0%	0.0%	4.3%	8.0%
2010 Q4	5431	5.7%	7.4%	0.0%	4.1%	7.7%
2011 Q1	5477	7.1%	8.5%	1.7%	5.4%	9.7%
2011 Q2	5520	7.3%	9.0%	1.8%	5.4%	9.8%
2011 Q3	5511	7.7%	9.0%	2.0%	5.8%	10.4%
2011 Q4	5529	14.5%	13.7%	4.2%	11.1%	21.9%

o Citations

1b.3. Provide citations for the evidence described above

The data analyses shown above represent unpublished analyses of this draft measure (from Medicare claims data) by the University of Michigan - Kidney Epidemiology and Cost Center and Arbor Research Collaborative for Health.

o Summary of data on disparities by population group

1b.4. Summarize evidence found that demonstrates any disparities. Describe groups in which disparities exist.

Investigations of hemoglobin less than 10 by race, sex, ethnicity, and age indicated relatively little variation and no substantial disparities among these groups.

Patient-level Demographics for 2011 Q1 (N=184,481)	
Strata	%Hgb < 10
Race	
American Indian/AK Native	5.49%
Asian/Pacific	6.37%
Black	7.81%
White	6.31%
Unknown	6.08%
Other/Multi-racial	7.07%
Sex	
Female	6.98%
Male	6.82%
Hispanic	
Yes	5.67%
No	7.13%
Unknown	6.79%
Age	
18-64	7.91%
65+	5.66%

- o **Citations**

1b.5. Provide citations for the evidence described above

The data analyses shown above represent unpublished analyses of this draft measure (from Medicare claims data) by the University of Michigan - Kidney Epidemiology and Cost Center and Arbor Research Collaborative for Health.

- ◆ **Evidence to Support Measure Focus**

- o **Structure-process-outcome relationship**

1c.1. Briefly state the measure focus (for example, health outcome, intermediate clinical outcome, process, structure) Then, identify the appropriate links (for example, structure-process-health outcome, process-health outcome, intermediate clinical outcome-health outcome)

The measure focus is an intermediate clinical outcome. The link is process-intermediate health outcome-health outcome. Changes in ESA use (process) may lead to lower achieved Hgb values (intermediate clinical outcome), which may result in poorer anemia management, higher risk of transfusions, and lower quality of life for patients (Health Outcomes).

- **Type of evidence**

- 1c.2. Describe the type of evidence, selecting from the following list all that apply:
- **Clinical practice guideline: YES**
- Selected individual studies (rather than entire body of evidence)
- **Systematic review of body of evidence (other than within guideline development): YES**
Other (state type of evidence)

- **Directness of evidence to the specified measure**

1c.4. State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population.

The current body of evidence has CKD patients that are both on and not on dialysis, whereas the target population for this measure is restricted to CKD patients on dialysis. Most studies have focused on different hemoglobin targets with regards to cardiovascular risk and quality of life endpoints. These studies have not addressed achieved Hgb values that mitigate the risk of transfusion.

- **Quantity of studies in the body of evidence**

1c.5. Total number of studies, not articles

In addition to the KDIGO Guidelines, UK-NICE guidelines and the FDA guidance, the measure developer and technical expert panel reviewed a comprehensive set of 31 articles on anemia management in dialysis patients published during 1990-2011.

- **Quality of body of evidence**

1c.6. Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address:

- a) Study design/flaws
- b) Directness/indirectness of the evidence to this measure (for example, interventions, comparisons, outcomes assessed, population included in the evidence)
Imprecision/wide confidence intervals due to few patients or events

The body of literature has moderate certainty that ESA use to treat severe anemia represents a benefit to ESRD patients in terms of avoiding transfusion and improving QoL. Many of the studies, however, are open-label or non-randomized designs, which limits the strength of the findings. However, these studies are directly related to the proposed measure given the similarity in patient population and outcome assessed.

- **Consistency of results across studies**

1c7. Summarize the consistency of the magnitude and direction of the effect across studies

- **Net benefit**

1c8. Provide estimates of effect for benefit/outcome, identify harms addressed and estimates of effect, and net benefit---benefit over harms across studies. Please include results of business/social/economic case for the measure.

Using ESAs to treat severe anemia should improve QoL and decrease the need for blood transfusions.

○ **Grading of strength/quality of the body of evidence**

1c9, 1c10, 1c11, 1c13, 1c14. Please address:

- *Indicate if the body of evidence has been graded*
- *If the body of evidence was graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias*
- *System used for grading the body of evidence*
- *Grade assigned to the body of evidence*
- *Summary of controversy/contradictory evidence*

The relevant KDIGO Guideline was given a “moderate” grade for quality of evidence.

○ **Citation**

1c15. Provide citations for the evidence described above

Please refer to section 1a4

○ **Guideline recommendation**

1c16. Quote verbatim, the specific guideline recommendation (Including guideline number and/or page number)

KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease

- 3.4.3: For adult CKD 5D patients, we suggest that ESA therapy be used to avoid having the Hgb concentration fall below 9.0 g/dl (90 g/l) by starting ESA therapy when the hemoglobin is between 9.0–10.0 g/dl (90–100 g/l).
- 3.4.4: Individualization of therapy is reasonable as some patients may have improvements in quality of life at higher Hb concentration and ESA therapy may be started above 10.0 g/dl (100 g/l). (Not Graded)

KDIGO Anemia Guidelines 2012: Guideline 4.1.3: When managing chronic anemia, we suggest that the benefits of red cell transfusions may outweigh the risks in patients in whom (2C):

- ESA therapy is ineffective (e.g., hemoglobinopathies, bone marrow failure, ESA resistance)
- The risks of ESA therapy may outweigh its benefits (e.g., previous or current malignancy, previous stroke)

KHA-CARI guideline

- Suggest that in dialysis patients with anemia due to CKD, an erythropoiesis-stimulating agent (ESA) can be used to prevent the hemoglobin falling below 95 g/L in order to avoid the need for blood transfusion and to improve quality of life.

NICE UK Anaemia Management in Chronic Kidney Disease Guidelines

- Typically maintain the aspirational Hb range between 10 and 12 g/dl for adults, young people and children aged 2 years and older, and between 9.5 and 11.5 g/dl for children younger than 2 years of age, reflecting the lower normal range in that age group.

- To keep the Hb level within the aspirational range, do not wait until Hb levels are outside the aspirational range before adjusting treatment (for example, take action when Hb levels are within 0.5 g/dl of the range's limits). [NICE 2011]
- Consider investigating and managing anaemia in people with CKD if:
 - Their Hb level falls to 11 g/dl or less (or 10.5 g/dl or less if younger than 2 years) or,
 - They develop symptoms attributable to anaemia (such as tiredness, shortness of breath, lethargy and palpitations). [NICE 2011]

- **Citation**

1c17. Provide citations for the clinical practice guideline quoted above

Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney inter., Suppl.* 2012; 2: 279–335.

McMahon LP and MacGinley R. KHA-CARI guideline: Biochemical and haematological targets: Haemoglobin concentrations in patients using erythropoietin-stimulating agents. *Nephrology* 2012;17(1):17-9.

NICE 2011: UK Anaemia Management in Chronic Kidney Disease Guidelines, No. 114 National Clinical Guideline Centre (UK). London: Royal College of Physicians (UK); February 2011.

- **URL**

1c18. National Guideline Clearinghouse or other URL

KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease

http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf

KHA-CARI guideline

<http://onlinelibrary.wiley.com/doi/10.1111/j.1440-1797.2011.01535.x/full>

NICE 2011 Guideline

<http://www.ncbi.nlm.nih.gov/books/NBK65530/>

- **Grading of strength of recommendation**

1c191 1c21, 1c23. Please address:

- *Has the recommendation been graded?*
- *System used for grading the strength of guideline recommendation (USPSTF, GRADE, etc.) Grade assigned to the recommendation*

The KDIGO Recommendation grading is “2B.” The KHA-CARI guideline to avoid the need for blood transfusion is “2B” and to improve quality of life is “2D.”

The KDIGO Guidelines used the GRADE system; the grades given are listed above with the relevant guidelines. The definitions used by KDIGO are listed below.

— **NOMENCLATURE AND DESCRIPTION FOR RATING GUIDELINE RECOMMENDATIONS**

Within each recommendation, the strength of recommendation is indicated as **Level 1**, **Level 2**, or **Not Graded**, and the quality of the supporting evidence is shown as **A**, **B**, **C**, or **D**.

Grade*	Implications		
	Patients	Clinicians	Policy
Level 1 'We recommend'	Most people in your situation would want the recommended course of action and only a small proportion would not.	Most patients should receive the recommended course of action.	The recommendation can be evaluated as a candidate for developing a policy or a performance measure.
Level 2 'We suggest'	The majority of people in your situation would want the recommended course of action, but many would not.	Different choices will be appropriate for different patients. Each patient needs help to arrive at a management decision consistent with her or his values and preferences.	The recommendation is likely to require substantial debate and involvement of stakeholders before policy can be determined.

*The additional category 'Not Graded' was used, typically, to provide guidance based on common sense or where the topic does not allow adequate application of evidence. The most common examples include recommendations regarding monitoring intervals, counseling, and referral to other clinical specialists. The ungraded recommendations are generally written as simple declarative statements, but are not meant to be interpreted as being stronger recommendations than Level 1 or 2 recommendations.

Grade	Quality of evidence	Meaning
A	High	We are confident that the true effect lies close to that of the estimate of the effect.
B	Moderate	The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
C	Low	The true effect may be substantially different from the estimate of the effect.
D	Very Low	The estimate of effect is very uncertain, and often will be far from the truth.

o **Rationale for using this guideline over others**

1c24. *If multiple guidelines exist, describe why the guideline cited was chosen. Factors may include rigor of guideline development, widespread acceptance and use, etc.*

KDIGO Clinical Practice Guidelines for Anemia in Chronic Kidney Disease, as well as the KHA-CARI and UK NICE guidelines are the most recently published guidelines. In addition, they were developed by an international consortium of dialysis experts using rigorous literature review and systematic grading methodology

o **Overall assessment of the body of evidence**

1c25, 1c26, 1c.27. *Based on the NQF descriptions for rating the evidence, what was your assessment of the following attributes of the body of evidence?*

- **Quantity High**
- **Quality Moderate**
- **Consistency High**

Reliability and Validity – Scientific Acceptability of Measure Properties

◆ **Reliability Testing**

o **Data sample**

2a2.1. *Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*

Reliability of the measure was assessed using data on ESRD patients over a one year period in 2011. Data for the measure are derived from an extensive national ESRD patient database, which is derived from Program Medical

Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The database is comprehensive for Medicare patients.

- o **Analytic methods**

2b2.2 .Describe method of validity testing and rationale; if face validity, describe systematic assessment

To assess reliability, we evaluated the degree to which the measure was consistent quarter to quarter. If one looks at two adjacent time intervals, one should expect that a reliable measure will exhibit correlation over these periods since large changes in patterns affecting the measure should not occur for most centers over shorter periods. Quarter to quarter variability in the measure values was assessed across all 4 calendar quarters of 2011.

- o **Testing results**

2a2.3. Provide reliability statistics and assessment of adequacy in the context of norms for the test conducted

The correlation between the measure across adjacent (previous and following) calendar quarters of 2011 (Q1 vs. Q2, Q2 vs. Q3, Q3 vs. Q4) ranged from 0.37 to 0.45, indicating that facilities with large or small measures tended to have larger or smaller measures in the previous and following quarter. These correlations were all highly statistically significant but the strength of this correlation diminishes over time, indicating variation in the measure.

The measure is based on complete data and is not subject to judgment or rater variability. Hence the measures of inter-rater variability are not relevant here.

- ◆ **Validity Testing**

- o **Data sample**

2b2.1. Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

N/A

- o **Analytic method**

2b2.2 .Describe method of validity testing and rationale; if face validity, describe systematic assessment

Using Medicare claims data for years 2010 and 2011, a Poisson regression analysis was performed with standardized mortality ratio (SMR) or standardized hospitalization ratio (SHR) by quintile levels of facilities with hemoglobin less than 10 g/dL. These were unpublished internal analyses performed by the University of Michigan - Kidney Epidemiology and Cost Center and Arbor Research Collaborative for Health.

In addition to the unpublished internal analyses, in May 2012 there was an assessment of face validity based on polling of a CMS Technical Expert Panel (TEP). The group considered using guidelines as a basis versus direct study evidence.

o **Testing results**

2b2.3. (Provide statistical results and assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)

The data analyses shown below represent unpublished analyses of this draft measure (from Medicare claims data) by the University of Michigan - Kidney Epidemiology and Cost Center and Arbor Research Collaborative for Health. A facility in the highest quintile of patients with Hgb < 10 for 2011 has a 9.55% higher SMR than the middle quintile range.

2010 Poisson Regression results SHR & SMR by Facility %Hgb < 10 quintiles						
%Hgb < 10 Quintile (%Range)	2010 SHR Poisson Estimate	Ratio	p-value*	2010 SMR Poisson Estimate	Ratio	p-value*
1 (< 2.08)	-0.0366	0.9641	0.0173	-0.0459	0.9551	0.0026
2 (2.08-3.65)	-0.0213	0.9789	0.1239	-0.0233	0.9770	0.0947
3 (Ref.) (3.65-5.35)		1.0000			1.0000	
4 (5.35-8.06)	0.0383	1.0390	0.0044	0.0266	1.0270	0.0516
5 (>8.06)	0.1168	1.1239	<.0001	0.0700	1.0725	<.0001

*Significant p-values (<0.05) in bold

2011 Poisson Regression results SHR & SMR by Facility %Hgb < 10 quintiles						
%Hgb < 10 Quintile (%Range)	2011 SHR Poisson Estimate	Ratio	p-value*	2011 SMR Poisson Estimate	Ratio	p-value*
1 (< 3.77)	-0.0305	0.9700	0.0425	-0.0403	0.9605	0.0083
2 (3.77-6.37)	-0.0190	0.9812	0.1725	-0.0240	0.9763	0.092
3 (Ref.) (6.37-9.14)		1.0000			1.0000	
4 (9.14-12.98)	0.0415	1.0424	0.0024	0.0335	1.0341	0.0179
5 (>12.98)	0.0765	1.0795	<.0001	0.0912	1.0955	<.0001

*Significant p-values (<0.05) in bold

Eligible Anemia TEP members cast votes for the Hgb threshold values of Hgb 9.5 g/dl and Hgb 10.0 g/dl; five members cast votes for 10, one vote was cast for 9.5.

◆ **Exclusions**

o **Data sample for analysis of exclusions**

2b3.1. Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

For the first quarter of 2011, the data represents 184,481 patients at 5477 facilities. These data are part of an extensive national ESRD patient database, which we derive from Program Medical Management and Information

System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The database is comprehensive for Medicare patients

o **Analytic method**

2b3.2. Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference

Patients are excluded from the measure if Medicare dialysis claims if on the first of the month the patient is fewer than 90 days since first ESRD service date, and if claims with hemoglobin values less than 5 or greater than 20 are indicated. Patients less than 18 years of age are excluded due to the relatively small number of pediatric patients treated at most facilities. To ensure quality in the calculation of the average hemoglobin in a calendar quarter, a patient must have 2 or more claims per facility with non-missing hemoglobin values. In addition, patients with the following comorbidity Medicare claims within one year prior to the observation period were excluded:

- Hemolytic and Aplastic Anemia
- Solid Organ Cancer (Breast, Prostate, Lung, Digestive tract and others)
- Lymphoma
- Carcinoma in situ
- Coagulation Disorders
- Multiple myeloma, Myelodysplastic Syndrome, and Myelofibrosis
- Leukemia
- Head and Neck Cancer
- Other Cancers (connective tissue, skin, and others)
- Metastatic Cancer
- Sickle cell anemia

o **Results**

2b3.3. Provide statistical results for analysis of exclusions (for example, frequency, variability, sensitivity analyses)

Of the patients identified for analysis in quarter 1 of 2011, 17.44% were excluded based on one or more of the comorbidities listed above..

Multivariate logistic regression with transfusion count as the dependent variable was performed to assess the predictive power of comorbidities on future transfusions, as a function of the time interval between development of the comorbidity and the occurrence of the transfusion. Transfusion count was coded as a binary variable (1 if transfusion). Result using 2011 data showed that 1-year look back period for each of the above mentioned comorbidities was a significant predictor of RBC transfusion events with odds ratio ranging from 1.2 to 3.2.

◆ **Risk Adjustment Strategy**

o **Data/ sample**

2b4.1. Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Delete row if measure is not risk adjusted.

N/A

- o **Analytic method**

2b4.2. Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables

N/A

- o **Testing results**

2b4.3. Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata. Delete row if measure is not risk adjusted.

N/A

- o **Rationale for no adjustment**

2b4.4. If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment. The three rows above may be deleted if this field is used. Delete row if measure is risk adjusted or if this is a process measure.

No risk adjustment is necessary. Patients with comorbidities that are associated with anemia and risk of transfusion have been excluded from reporting.

- ◆ **Identification of Meaningful Differences in Performance**

- o **Data/ sample**

2b5.1 Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

Data for the measure are derived from an extensive national ESRD patient database, which is derived from Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The database is comprehensive for Medicare patients.

- o **Analytic method**

2b5.2. Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance

N/A

- **Testing results**

2b5.3. Results-Provide measure performance results/scores (for example, distribution by quartile, mean, median, SD, etc.); identification of statistically significant and meaningfully differences in performance

N/A

- ◆ **Comparability of Multiple Data Sources/Methods**

- **Data/ sample**

2b6.1. Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

N/A

- **Analytic method**

2b6.2. Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure

N/A

- **Testing results**

2b6.3. Provide statistical results (for example, correlation statistics, comparison of rankings) and assessment of adequacy in the context of norms for the test conducted

N/A

- ◆ **Disparities in Care**

- **Stratification**

2c.1. If measure is stratified for disparities, provide stratified results (scores by stratified categories/cohorts)

N/A

- **Rationale for no stratification**

2c.2. If disparities have been reported/identified, but measure is not specified to detect disparities, please explain.

N/A

- **Supplemental information**

2.1. Supplemental testing methodology information: If additional information if available, please indicate where this information can be found: appendix, attachment, or URL

N/A

Usability◆ **Public Reporting**○ **Meaningful, understandable and useful**

3a.1. Use in public reporting---disclosure of performance results to the public at large (If used in a public reporting program, provide name of program(s), locations, Web page URL(s). If not publicly reported in a national or community program, state the reason and plans to achieve public reporting, potential reporting programs or commitments, and timeline, for example, within 3 years of endorsement)

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (for example, focus, group, cognitive testing) describe the data, method and results.

The measure results can act as a useful monitoring tool for facilities' to guard against under-use of ESA and the proportion of patients at increased risk for transfusion. Potential reporting of the measure in the Dialysis Facility Reports or Dialysis Facility Compare could provide stakeholders an opportunity to monitor the measure and compare their results to other facilities at the national and regional levels.

◆ **Quality Improvement**○ **Meaningful, understandable and useful**

3b.1. Use in QI (If used in quality improvement program, provide name of program(s), locations, Web page URL(s))

3b.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (for example, QI, initiative) describe the data, method and results

Facilities that observe increases of the measure over time may be able to identify improvement needs in their anemia management practices.

○ **Other accountability uses**

3.2. Use for other accountability functions (payment, certification, accreditation) (If used in a public accountability program, provide name of program(s), locations, Web page URL(s)). This row may be deleted if not applicable.

Feasibility◆ **How the data elements needed to compute measure score are generated**

4a.1. How are the data elements needed to compute measure scores generated? State all that apply. Data used in the measure are:

- *Generated by and used by health care personnel during the provision of care (for example, blood pressure, lab value, medical condition)
Coded by someone other than person obtaining original information (for example, DRG, ICD-9 codes on claims)*
- *Abstracted from a record by someone other than person obtaining original information (for example, chart abstraction for quality measure or registry) Other*

Data used in the measure are obtained from Medicare claims generated by and used by health care personnel during the provision of care, i.e. lab values, medical conditions and claims data.

◆ **Electronic availability**

4b.1. Are the data elements needed for the measure as specified available electronically (elements that are needed to compute measure scores are in defined, computer-readable fields)?

- *ALL data elements in electronic claims*

◆ **Susceptibility to inaccuracies, errors, or unintended consequences**

4c.1. Identify susceptibility to inaccuracies, errors, or unintended consequences of measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results.

◆ **Data collection strategy**

4d.1. Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (for example fees for use of proprietary measures)

The data are from Medicare (Part A and Part B) institutional claims.

Related Measures

◆ **Harmonization**

5a.1. If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized? If so, describe.

Our proposed intermediate clinical outcome measure is closely harmonized with an already endorsed physician-level measure with the same measure focus (but with a pediatric population):

- NQF #1667: (Pediatric) ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL

The proposed measure is also closely harmonized with a similar measure used for public reporting on Dialysis Facility Compare which is not currently NQF-endorsed, with the exception of using a 3-month time period as opposed to a 12-month time period.

◆ **Similar measures**

5b.1. *If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s) or other measures in current use, describe why this measure is superior to existing measures (for example, a more valid or efficient way to measure quality); OR, provide a rationale for the additive value of developing and endorsing an additional measure. (Provide analyses when possible.)*

Compared to a 12-month measure as has been used for public reporting on Dialysis Facility Compare, a 3 month time frame was selected as it is more sensitive in detecting low hemoglobin values.

○ **Citation**

Hirth RA, Turenne MN, Wheeler JRC, Ma Y, Messina JM. **Do resource utilization and clinical measures still vary across dialysis chains after controlling for the local practices of facilities and physicians?**. *Med Care*. 2010;48(8):726–732

Sample Dialysis Facility Compare Preview Report and Guide including measure calculation:
<http://www.dialysisreports.org/Methodology.aspx>