KIDNEY CARE QUALITY ALLIANCE

ANEMIA WORKGROUP MEETING 1 SUMMARY
JULY 8, 2022

Attendees: Todd Berner, MD; Steven Fishbane, MD; Eric Weinhandl, PhD, MS; Wendy St. Peter, PharmD; Keyan Javadi, MPH; Craig Schneider, PhD; Kathy Lester, JD, MPH; Lisa McGonigal, MD, MPH

Not Present: Henry Cremisi, MD; Lori Hartwell

BACKGROUND AND CHARGE

Dr. McGonigal began the meeting by announcing the transition to a new facilitation team. After roll call and introductions, Dr. Schneider reviewed the meeting agenda and provided an overview of the 2021-2022 KCQA Project, including the Workgroup's scope and charge.

Project Overview

Dr. Schneider summarized that in 2005, Kidney Care Partners (KCP) launched the Kidney Care Quality Alliance (KCQA) as a quasi-independent measure development entity. KCQA develops dialysis facility-level performance metrics for National Quality Forum (NQF) endorsement to address absent or faulty measures deployed in CMS's ESRD Quality Incentive Program (QIP), Five-Star Program, and now also the ESRD Treatment Choices (ETC) Model. In June 2021, KCQA launched a new project cycle to develop metrics in five clinical priority areas consistently identified by KCP members as being particularly problematic in these federal programs: home dialysis, transplant, anemia, bone mineral metabolism, and bloodstream infection. Consistent with KCQA's Guiding Principles, the measures will be community-supported, empirically sound, actionable, patient-centric, will appropriately address social risk and health inequities, and will meet the needs of patients, providers, other members of the kidney care community, and federal policymakers.

Anemia Project Scope

In accordance with KCQA's mission to meet the needs of our stakeholders, Dr. Schneider indicated that KCP has long held the position that the existing QIP anemia management measure, the Standardized Transfusion Ratio Measure (NQF 2979) is an inappropriate measure of performance within dialysis facilities. Specific issues include the following:

- **Poor Reliability:** Initial STrR measure testing demonstrated inappropriately low reliability estimates for small facilities, wherein nearly 60 percent of a facility's score was found to be attributable to random noise. In the most recent endorsement maintenance review, overall reliability remained adequate (IUR 0.6) but reliability by facility size was not provided because it was "not required by NQF." It was thus necessary to conclude that performance in small facilities had not appreciably improved in the interim.
- **Poor Validity:** Soon after the measure's initial endorsement in 2016, it became clear during operationalization that the codes specified in the measure did not accurately capture a sufficient percentage of blood transfusions to ensure validity of the measure for use within the QIP. CMS acknowledged the problem and subsequently converted the STrR to a reporting measure beginning in PY 2022 while examining the issue. We note in the recently released Proposed Rule, CMS indicates that the validity issues have now been resolved and the measure will be re-deployed as a clinical metric in PY 2025.
- **Ratio vs Rate Construct:** KCP has consistently advocated for use of true rate measures over the risk-standardized ratio measures frequently developed and adopted by CMS. The ratio measures, including the STrR, have been found to have relatively wide confidence intervals that can lead to facilities' performance being misclassified. KCP has suggested CMS use the underlying transfusion rate and appropriately risk adjust it for race and ethnicity, as is done with the SMR.
- **Hemoglobin Measure More Appropriate for Use in Dialysis Facilities:** Finally, because of the inability of dialysis facilities to directly influence hospital transfusion practices, KCP has consistently recommended that CMS should replace the STrR with a hemoglobin threshold metric such as the Hb <10 g/dL measure. While such a measure is not currently endorsed, NQF's updated evidence algorithm would provide a path for its

consideration anew. Prior iterations of Hb threshold measures represent a framework upon which updated specifications, exclusions, and business rules could be built.

Workgroup Charge

Dr. Schneider indicated that over the next 4-6 weeks, the Anemia Workgroup will first identify an anemia management measure concept, and from there measure specifications (numerator, denominator, exclusions) with risk adjustment and/or stratification approaches (if deemed necessary). The KCQA Steering Committee will work collaboratively with the Workgroup, iteratively reviewing and either approving the Workgroup's recommendations or remanding them for revisions.

Workplan and Timeline

Dr. Schneider next reviewed the detailed Anemia Workplan and Timeline. He noted that it is essential for the Workgroup to proceed expeditiously for KCQA to meet anticipated deadlines; the fully specified measures must be available no later than mid-August. The overall, high-level workflow in the coming 4-6 weeks is as follows:

1. **Meeting 1: Identify Candidate Concept and Preliminary Measure Specifications.** The first meeting (July 8) will focus on the identification of the candidate measure concept and preliminary draft measure specifications for the Steering Committee's consideration. To facilitate this process, staff has provided a summary table of ESRD anemia management measures that have been previously endorsed and/or used in CMS's quality programs. We have also drafted a measure "prototype" to be used as a starting point for the Workgroup's deliberations.
2. **Meeting 2: Develop Measure Specifications.** For the second meeting (July 22), the Workgroup will continue to define and refine the preliminary numerator, denominator, and exclusions. These draft concept/specifications will subsequently be reviewed by the Steering Committee for approval, with or without recommended revisions.
3. **Meeting 3 (and 4, if needed): Complete Specifications and Assess Need for Risk Adjustment/Stratification**. In its third (and forth, if needed) meeting(s) (TBD), the Workgroup will finalize the measure specifications and will consider and make recommendations on the need for risk adjustment and/or stratification to appropriately address clinical and social risk variables. It is not expected that the Workgroup will be involved in the *development* of a risk model, but rather will generate recommendations on a measure's perceived *need* for adjustment and/or stratification, as well as potential variables for consideration.

   The resulting completed measures will then be reviewed by the Steering Committee and full KCQA for approval to advance to the measure testing phase of the project, which will take place in the fall.

At this point (mid-August), Dr. Schneider indicated that the KCQA Anemia Workgroup will adjourn but may be asked to weigh in (likely via email) on any issues that arise during measure testing this fall. Like Steering Committee and KCQA members, the Workgroup may also be asked to review the NQF submission materials (anticipated date December 2022).

NQF ENDORSEMENT CRITERIA

Next, Dr. Schneider noted, KCQA develops measures with an eye towards NQF endorsement. As such, it is important that the Workgroup keep the NQF criteria in mind as it considers candidate concepts and then measure specifications. The four primary NQF criteria are:

1. **Importance to Measure and Report (Evidence).** The extent to which:
   a. the measure focus is evidence-based;
   b. the measure focus is important to making significant gains in healthcare quality; and
   c. there is variation in or overall less-than-optimal performance.
2. **Scientific Acceptability of Measure Properties.** The extent to which the measure would produce consistent (reliable) and credible (valid) results related to quality of care.
3. **Feasibility.** The extent to which the specifications, including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

4. **Usability.** The extent to which potential audiences (e.g., patients, providers, purchasers, policymakers) could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

Dr. Schneider indicated that each NQF criterion has several sub-criteria, summarized in detail on NQF's website. Workgroup members are not expected to be experts in the NQF evaluation criteria, in particular the sub-criteria. During the Workgroup's deliberations, however, KCQA staff are likely to refer to them and/or query or press Workgroup members as to relevancy of x, y, or z to meeting the criteria.

Other Anemia Management Measures

Dr. Schneider next reviewed the Other Anemia Management Measures, which staff has provided a summary table of ESRD anemia management measures that have been previously endorsed and/or used in CMS's quality programs. The table details six such measures:

1. **Standardized Transfusion Ratio (STrR, NQF 2979);** CMS, currently NQF-endorsed.
2. **Monthly Hb Measurement for Pediatric Patients (NQF 1424);** CMS, currently NQF-endorsed.
3. **Pediatric Kidney Disease: ESRD Patients with Hb <10 g/dL;** RPA, retired in 2022.
4. **Monitoring Hb Levels Below Target Minimum;** CMS, retired in 2012 following FDA boxed warning and replaced with STrR.
5. **Adult Kidney Disease: Patients on ESA with Hb >12 g/dL;** RPA, retired (year?).
6. **Assessment of Iron Stores;** CMS, retired in 2011.

Hemoglobin Threshold Measure Evidence (preliminary)

Dr. Schneider next reviewed the hemoglobin threshold measure evidence. He informed the Workgroup that the blood transfusion rates among Medicare dialysis beneficiaries peaked in January 2013 at 4.6% of patients per month receiving at least one transfusion, then steadily decreased through the fourth quarter of 2019 to 3.1%. However, a blood transfusion rate measure such as the STrR is necessarily a blunt instrument, leaving significant room for improvement in the "upstream" management of anemia in ESRD. According to the USRDS 2021 Annual Data Report,[1] an average of 23.5% of all hemodialysis patients each month in 2019 had a hemoglobin value <10 g/dL (irrespective of ESA use), with 8.0% each month falling below 9 g/dL. Findings were similar for peritoneal dialysis; in 2018, an average of 23.8% of all PD patients each quarter had Hb values <10, again with 8.0% falling below 9 g/dL. These values were largely consistent across racial and ethnic groups, with some exceptions; anemia was slightly *less* prevalent among HD patients of Hispanic ethnicity (20.5%) and *more* prevalent in Black and Asian PD patients (approximately 29% and 28%, respectively).

Both the FDA and current Kidney Disease Improving Global Outcomes (KDIGO) guidelines recommend the initiation of ESAs for patients with CKD 5D at a Hb threshold of <10 g/dL[2,3] KDIGO advises against allowing the Hb to fall below 9 and recommends addressing all correctable causes of anemia (including iron deficiency and inflammatory states) prior to initiation of ESA therapy. The FDA boxed warning indicates ESAs should be reduced or interrupted when the Hb level approaches or exceeds 11 g/dL because of increased risk of major adverse cardiovascular events (MACE)—although the Hb target that best balances benefits and risks has never been identified for any of the ESAs. (Of note, USRDS reports an average of 13.3% of all HD patients in 2019 had Hb ≥12 g/dL each month, and 20.0% of all PD patients had Hb values ≥12—approximately 50% higher than in hemodialysis patients.)

The proposed KCQA prototype measure merely establishes a lower Hb threshold below which action should be considered and is deliberately silent on treatment options.

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[1] USRDS. 2021 Annual Data Report.

[2] FDA. Roxadustat Briefing Document. July 15, 2021.

[3] KDOQI. KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guideline for Anemia in CKD. *Am J Kidney Dis.* 2013;62(5):849-859.

Anemia Measure Prototype
Dr. Schneider next reviewed the prototype measure drafted by staff for the Workgroup's to be used as a starting point for the Workgroup's deliberations. The intent of the prototype is to stimulate discussion and kick off the consensus process. As noted above, KCP has consistently recommended that CMS should replace the STrR with a hemoglobin threshold metric such as the Hb < 10 g/dL measure. While such a measure is not currently endorsed, NQF's updated evidence algorithm would provide a path for its consideration anew. Prior iterations of Hb threshold measures represent a framework upon which updated specifications, exclusions, and business rules could be built.

Identification of Measure Concept and Draft Specifications
The Workgroup spent the majority of the first meeting identifying its prioritized measure concept and preliminary specifications for Steering Committee consideration. The Prior Anemia Management Measures Table, Measure Prototype, and Workgroup members' own insights and expertise will inform this discussion. If consensus is not reached in this regard, the Steering Committee will be asked to weigh in to provide additional guidance to the Workgroup.

DISCUSSION

The measure concept identified by the Workgroup are described below, along with a brief summary of the discussion and decisions.

Concept: Hemoglobin <10 g/dL

- *Discussion Points:*
    - Workgroup members agreed that the prototype measure should be <10 g/dL. Some suggested if a range between 10-12 g/dL would be acceptable. However, a range might not be appropriate since there are concerns that it might push patients' levels too high.
    - The workgroup expressed a desire to reduce the rate of transfusions and improve quality of life.
    - Is there sufficient evidence to support a measure of <10g/dl? We need strong data to withstand the scrutiny that will be applied.
    - The testing process will determine the extent of variability across dialysis facilities.
    - It was noted that the Hb<10 measure relies on observational data – the workgroup should determine whether the members are comfortable with such an approach. Another data issue is that the evidence is not based on randomized control trial – this is not unusual for dialysis care, but the workgroup may want to add a justification for its proposed approach.
    - There are technical problems with using transfusion rates as a quality indicator. The challenge at the present time is to have a quality-of-life measure – the proposed Hb measure is the sweet spot.
    - This approach makes sense as in interim step but in the long run we should try to move towards a patient-reported outcome measure. We should continue efforts to develop a PROM.

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Dr. Schneider concluded the meeting by reviewing next steps:

- The Anemia Workgroup will reconvene on July 22nd to continue drafting specifications.
- The Steering Committee will meet on early August 9th to review/approve recommended measure concept(s) and preliminary specifications.
- The Anemia Workgroup will reconvene in early August to continue to finalize measure specifications, based on Steering Committee input.

KIDNEY CARE QUALITY ALLIANCE

ANEMIA WORKGROUP MEETING 2 SUMMARY
JULY 22, 2022

Attendees: Todd Berner, MD; Steven Fishbane, MD; Lori Hartwell; Eric Weinhandl, PhD, MS; Wendy St. Peter, PharmD; Keyan Javadi, MPH; Michele Kimball; Kathy Lester JD, MPH; Lisa McGonigal MD, MPH; Craig Schneider, PhD

Not Present: Henry Cremisi, MD

MEETING SUMMARY
After welcoming remarks and roll call, Dr. Schneider reviewed the meeting agenda. The Workgroup then reviewed staff's summary of its Meeting 1 discussion/decisions and agreed to review and approve the summary following the meeting. The Workgroup also considered the draft prototype measure developed by staff through a synthesis of prior measure efforts:

- **Measure 1: Hemoglobin <10 g/dL**

The group's discussion and decisions are summarized below.

Meeting 2 Decisions Summary:
- Numerator:
  - Adding that number of patient-months from the denominator during which the patient has a Hemoglobin <10 will be the first measure taken during that month
  - For patients that have several measures taken during the month, the data used will be for the first measurement taken during the month
- Denominator:
  - No changes
- Exclusions:
  - Adding for the first bullet: B12 deficiency, folic deficiency, or iron deficiency are not permissible exclusions
  - No changes to second bullet
  - Third bullet: patients who initiated dialysis <90 days
  - Fourth bullet: transient patients- less than 7 treatments and define that this is what "transient" means in the specifications
  - Fifth bullet: Ask CDRG to test for validity/reliability. Group prefers less than <25 for patients during the measurement month but CMS has expressed a preference for <11 in the past.
- Risk adjustment or stratification measures
  - Ask CDRG to test to see if an adjustment for race is appropriate

General Discussion Points:
- Stress there should be a mid-week draw on patients so there is less variability between dialysis facilities. If someone wants a higher Hgb result, they will suggest to draw it on Monday as there is an extra day between dialysis treatments after the weekend. Ideally, the facilities would take the measure on a Wednesday or Thursday.
- Exclusions
  - Not acceptable as documentation to have deficiency in anemia. These patients should not be excluded in the measure. Keep these patients in the measure.
  - Clarification note regarding the definition of "transient"
  - 4th exclusion currently has an X in it.
    - Average number of patients a month
    - Average <25?

        - Ask CDRG to test the statistical reliability of the minimum number of average patient-months for inclusion in the measure
- Difference in race difference in hemoglobin levels over time
- Standard transfusion level
- Address disparities?
    - Disparity amongst different race groups. Is it something we can add in as a component for evaluation?
    - KCP has tried to stratify vs risk adjust
- Pandemic rules
    - You would have a 30-day gap
    - Avoid the transient patients
- Exclude the patients who have initiated treatment less than 90 days
- There is a definition for transient patients (less than 7 treatments) – include this definition in the specifications
- Evidence
    - Bullet 6 is not really evidence
    - Will this slide be used for outside uses?
        - Suggestion to clean it up
        - Divide up into evidence and then guidance?
    - We need to bring in some of the quality-of-life evidence that may strengthen our workgroup's case for the proposed measure
        - Hgb and quality of life
        - Hgb level and cardiovascular outcomes…observation data (not sure if we can use this for NQF). Lower Hgb have increased risk.
        - Safety issues that go into Hbg level >13
    - https://www.healthmanagement.com/wp-content/uploads/HMA-Value-of-Managed-Care.pdf
        - Consider evidence from other countries
        - Consider management of patient's fluid levels

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Dr. Schneider concluded the meeting by reviewing next steps:

- Anemia workgroup will reconvene sometime the first week of August (date TBD and TBD whether a fourth meeting will also be necessary).
- Steering Committee will meet on August 9th to review/approve recommended measure concept(s) and preliminary specifications
- Prior to the next meeting, Workgroup members will think about risk adjustment or stratification approaches to include in the measure specifications.
- Prior to the next meeting, Workgroup members will review the "evidence" slide and suggest any changes or additional evidence to include and distinguish between content that is best practice guidelines and content that is peer-reviewed evidence.