

Public Comment Summary Report

Project Title:

End Stage Renal Disease (ESRD) Dialysis Facility Compare (DFC) Star Ratings Technical Expert Panel (TEP)

Dates:

- The Call for Public Comments ran from October 5, 2016 to December 7, 2016.
- The Public Comment Summary was made available on May 10, 2017.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to review the methodology developed to produce the DFC Star Ratings. The contract name is the ESRD Quality Measure Development, Maintenance, and Support contract. The contract number is HHSM-500-2013-130171.

In April 2015, a Star Rating TEP was convened to review the DFC Star Rating methodology. As a result of TEP deliberations, several updates to the methodology were implemented. During the October 5, 2016 National Provider Call, CMS announced a star rating TEP would be convened in 2017. CMS proposed candidate measures for future inclusion on the DFC website and in the DFC Star Ratings at the October 5, 2016 National Provider Call. CMS requested Public Comment on the inclusion of additional measures to the Dialysis Facility Compare (DFC) website in order to (1) increase transparency in the process and selection criteria, (2) allow for increased input from the community on candidate measures, and (3) increase the opportunity for the inclusion of externally developed measures on DFC.

CMS requested public comments on the following:

- DFC measure candidates
- DFC measure updates
- Star Ratings measure candidates
- Star Ratings measure updates
- Additional measures candidates for DFC or Star Ratings
- Star Ratings scoring methodology and reporting

DFC October 2018 Release: Measure Candidates

New Measures

- Measurement of nPCR for Pediatric HD Patients (NQF# 1425)

Updating Existing Measures

- Standardized Mortality Ratio (SMR, NQF #0369)
- Standardized Hospitalization Ratio (SHR, NQF #1463)
- Standardized Transfusion Ratio (STrR, NQF #2979)
- Standardized Fistula Rate (NQF# 2977) – Replacing measure NQF#0257
- Long-Term Catheter Rate (NQF# 2978) – Replacing measure NQF#0256

In addition to the proposed updates to the measures reported on DFC, CMS is also requesting comment on measures proposed for inclusion in the DFC 2018 Star Ratings.

Measures Considered for DFC Star Ratings for October 2018 Rollout

New Measures to the DFC Star Ratings

- Standardized Readmission Ratio (SRR, NQF# 2496)
- Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V (Pediatric PD Kt/V, NQF# 2706)
- In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS, NQF# 0258)
- NHSN Dialysis Event Surveillance Bloodstream Infection (BSI) Standardized Infection Ratio (SIR) Measure NHSN Bloodstream Infection (NHSN SIR, NQF# 1460)

Measure Updates to the DFC Star Ratings

- Standardized Mortality Ratio (SMR, NQF #0369)
- Standardized Hospitalization Ratio (SHR, NQF #1463)
- Standardized Transfusion Ratio (STrR, NQF #2979)
- Standardized Fistula Rate (NQF# 2977)
- Long-Term Catheter Rate (NQF# 2978)

Measures for removal

- Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (NQF #0257)
- Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access (NQF #0256)
- SMR (as reported on DFC 2016 Release)
- SHR (as reported on DFC 2016 Release)
- STrR (as reported on DFC 2016 Release)

Information About the Comments Received:

- Public comments were solicited by email.
- Four public comments were received.

Stakeholder Comments—General and Measure-Specific

Comments on the Star Rating Methodology and Reporting

Several commenters expressed support for the TEP recommended updates to the star ratings that were adopted such as using z-scores for measure scoring, and reflecting improvement in scoring. The commenters expressed support for the transparency and the measure implementation process that allowed for public comment and review of the candidate measures before implementing the measures into the star ratings. The commenters expressed questions around future re-baselining of the star ratings.

Response: Thank you for your comments. As stated in the 2017 DFC Star Rating TEP charter, one of the TEP objectives is for the TEP to provide recommendations on re-baselining the star ratings.

Comments on the Pediatric PD Kt/v

Several commenters supported the Pediatric PD Kt/V measure for inclusion in the Star Ratings.

Response: Thank you for your comments.

Comments on the ICH-CAHPS

Several commenters recommended that the ICH-CAHPS not be included in the DFC Star Ratings due to issues with how the measure is currently administered. Commenters identified several barriers to the ICH-CAHPS measure such as low response rate, survey length, patient and facility burden, administration twice a year, and the exclusion of home hemodialysis patients. Commenters displayed general support for including the ICH-CAHPS on a separate DFC webpage but not for inclusion into the star rating.

Response: Thank you for your comments. Your comments have been passed on to the CMS ICH-CAHPS group.

Comments on the NHSN SIR

Several commenters recommended that the NHSN SIR measure not be considered for inclusion in the DFC Star Ratings until the issue of the underreporting of infections is resolved. Commenters stressed the importance of reducing infections, but recommended not considering this measure until the data are validated.

Response: Thank you for your comments. Your comments have been passed on to the CDC NHSN SIR group.

Comments on the SRR

Several commenters recommended that the SRR measure not be considered for inclusion in the DFC Star Ratings. The commenters expressed concerns about facility attribution, non-facility contributing factors, and measure reliability.

Response: *Thank you for your comments. The measure was designed to optimize care coordination and incentivize early action on the part of outpatient providers. We acknowledge the concerns about attribution. The measure has been reviewed by the National Quality Forum (NQF), and revised based on stakeholder feedback to exclude the first 3 days which satisfied the concerns about facility attribution. As the dialysis community commented, virtually all patients would present to their outpatient dialysis facility for treatment within the first 3 days after hospital discharge.*

Comments on the Additional Measure Candidates

One public commenter recommended that new patient reported outcomes should be produced for potential inclusion in the DFC Star Ratings.

Response: *We thank you for your comments. UM-KECC is in the process of convening a Patient Reported Outcomes (PRO) TEP later in 2017 in order to make recommendations for PRO measure development.*

Comments on the Vascular Access (Catheter and Fistula) measures

Several commenters supported the new Catheter and Fistula measures. One commenter did state that clarity around sole access would be helpful for this measure; and that the measure should account for prior failed vascular access attempts.

Response: *We thank you for your comments. The intent of the fistula measure, as recommended by the TEP, is to only include patients in the numerator if they are using an AVF as the sole means of access without presence of a dialysis catheter. Unfortunately, the current vascular access definitions in CROWNWeb do not support the ability to report presence of a catheter that is not in use. The "AVF Only" option in CROWNWeb specifies that two needles are being used, but does not explicitly indicate that no dialysis catheter is present. This scenario occurs infrequently. CMS intends to refine the definitions for the vascular access options in CROWNWeb so that "AVF only" will not include cases where a catheter is present but not in use. For additional clarity, the option in CROWNWeb that indicates "AVF with catheter" is intended to report when one lumen of the catheter is being used and one needle is used in the AVF. Patients reported under this option are not considered to have fistula as sole source for vascular access and are not included in the measure numerator.*

Multiple prior failed vascular access attempts were considered by the TEP as a potential exclusion criterion, however consensus was not reached within the TEP on how best to implement this exclusion. At the present time, as historical vascular access data in CROWNWeb are limited, the

measure uses ESRD vintage as a surrogate for the number of prior vascular accesses. We do intend to evaluate adjustment for the number of prior vascular accesses when more historical vascular access data are available.

The ability to determine the presence of a cardiac device from Medicare claims is limited as the laterality of the device is not apparent. We anticipate this level of specificity will improve with the change and availability of ICD-10 codes. Therefore, this and other comorbidities will be evaluated in the future as Medicare claims with ICD-10 data become available.

The C-statistic of 0.74 is considered to be adequate for the assessment of discriminative power of the model based on published literature, and is similar in magnitude to other current NQF endorsed quality measures that have been implemented by CMS; see the peer-reviewed references below that report similar C-statistics. In addition, the standardized fistula model was reviewed and endorsed by the TEP, providing both face validity and an element of peer review for the measure.

1. *Abbott K, Trespalacios F, and Agodoa L. Arteriovenous fistula use and heart disease in long-term elderly hemodialysis patients: Analysis of United States renal data system dialysis morbidity and mortality wave II. J Nephrol 2003; 16: 822-830.*
2. *Hurst et al. Arteriovenous Fistulas among Incident Hemodialysis Patients in Department of Defense and Veterans Affairs Facilities. J Am Soc Nephrol 21: 1571–1577 2010.*
3. *Michael P. Lily et al. 2012. Prevalence of Arteriovenous Fistulas in Incident Hemodialysis Patients: Correlation With Patient Factors That May Be Associated With Maturation Failure. American Journal of Kidney Diseases. April 2012 Volume 59, Issue 4, Pages 541–549.*
4. *Lok C et al. Risk Equation Determining Unsuccessful Cannulation Events and Failure to Maturation in Arteriovenous Fistulas (REDUCE FTM I). J Am Soc Nephrol 17: 3204–3212, 2006.*
5. *Masengu A, Maxwell A, Hanko J. AVF Failure to mature Investigating clinical predictors of arteriovenous fistula functional patency in a European cohort. Clinical Kidney Journal, 2016, vol. 9, no. 1, 142–147.*
6. *Nee et al. Impact of Poverty and Health Care Insurance on Arteriovenous Fistula Use among Incident Hemodialysis Patients. Am J Nephrol 2015;42:328–336*

Comments on the SMR measure

Public commenters offered differing opinions on the SMR measure. One commenter recommended that it be removed from the star ratings. Another commenter supported the SMR measure with the updates. A third commenter stated concerns about the measure's reliability.

Response: *We thank you for your comments. On the NQF Public Comment call on September 23, 2016, the committee decided to recommend endorsement of the SMR.*

The four-year SMR measure reliability reported in the NQF submission [overall Inter-Unit Reliability (IUR) of 0.59] is in the same range as other NQF-endorsed quality measures (e.g. #0229 Heart failure measure, ICC: 0.55; #0468 Pneumonia mortality measure, ICC: 0.79; #1893 COPD mortality measure, ICC: 0.51; #2558 CABG mortality measure, ICC: 0.32). The reported IUR satisfied the

NQF's reliability and overall scientific acceptability criteria, reflected in the Renal Standing Committee recommendation to endorse this measure.

Comments on the SHR measure

One public commenter expressed support for the updated SHR measure. Another commenter expressed concerns about the measures reliability.

Response: *We thank you for your comments.*

The SHR measure reliability reported in the NQF submission (overall IUR of 0.70-0.72) is in the same range or higher than other NQF-endorsed quality measures (e.g. #0229 Heart failure measure, ICC: 0.55; #0468 Pneumonia mortality measure, ICC: 0.79; #1893 COPD mortality measure, ICC: 0.51; #2558 CABG mortality measure, ICC: 0.32). The reported IUR satisfied the NQF's reliability and overall scientific acceptability criteria, reflected in the Renal Standing Committee recommendation to endorse this measure.

Comments on the STrR measure

One commenter expressed support for the updated STrR measure. Other commenters stated concerns about the measure's reliability, and that this measure may be influenced by many factors outside of the facility's control.

Response: *We thank you for your comments. STrR measure reliability was reviewed in detail at the NQF Renal Standing Committee's meeting in June, 2016. The STrR measure reliability reported in the NQF submission (overall IURs of 0.60-0.66) is in the same range or higher than other NQF-endorsed quality measures (e.g. #0229 Heart failure measure, ICC: 0.55; #0468 Pneumonia mortality measure, ICC: 0.79; #1893 COPD mortality measure, ICC: 0.51; #2558 CABG mortality measure, ICC: 0.32). The measure satisfied NQF's reliability and overall scientific acceptability criteria, reflected in the Renal Standing Committee recommendation to endorse this measure.*

The commenter points out that a potential source of variation for claims-based identification of transfusion events lies in variation in claims submission by healthcare providers. This variation was present in the 2015 version of STrR. In the 2016 revision of the STrR submitted to NQF and recommended for endorsement by the NQF Renal Standing Committee, a more restricted definition of transfusion events is used, that, by definition, reduces this potential source of variability in claims submission by excluding transfusion events coded by less robust means. It is important to note that this specification change has minimal impact on the flagging of dialysis facilities as "worse than", "as expected" and "better than expected," suggesting that the issue raised by the commenter is not very impactful for this measure.

Regarding the separate issue of general attribution of transfusion events to dialysis facility processes and outcomes, the NQF Renal Standing Committee considered this issue as one of the fundamental criteria required by NQF for measure approval, and recommended approval after reviewing evidence submitted by the measure developer documenting the relationship between dialysis facility processes and anemia management outcomes and subsequent transfusion risk.

Furthermore, many newer quality measures are designed to incentivize coordinated care, including hospitalization and re-hospitalization metrics approved by the NQF for multiple provider types. A dialysis facility transfusion metric similarly incentivizes transfusion avoidance that is a consequence of inadequate anemia management by dialysis facilities in a clinical context where blood loss is occurring or is anticipated in another care venue. The immediate clinical indication to transfuse blood may be beyond the control of the dialysis facility, but ultimately the need for transfusion depends both upon that immediate clinical situation and the dialysis facility's underlying anemia management.

Comments on the Standardization of claims submission

One commenter recommended that CMS needs to improve its standardization of claims submission.

Response: We thank you for your comments.

Update of the Hypercalcemia Measure

The specifications for the Hypercalcemia Measure (NQF 1454) were updated in December 2016. These updates were submitted to NQF in December 2016, and they were accepted by NQF in January 2017. These changes are considered a non-substantive update by the National Quality Forum. As the measure update was not completed or approved by NQF prior to the National Provider Call (NPC) for Public Comments in October 2016, it was not announced on the October 2016 NPC or included in the list of measures for public comment for the DFC Star Rating. Because it was not included in the October 2016 NPC, CMS decided to obtain input from the Star Rating TEP, since the timing of implementing the updated measure on DFC and in the Star Ratings has implications for the Star Rating re-baselining. Details about the change to the measure and TEP feedback are described in the following sections.

Revisions to Specifications

The “proportion of patients with hypercalcemia” measure (NQF #1454) is the percentage of adult dialysis patients (Medicare and non-Medicare patients) with a 3-month rolling average of total uncorrected calcium (serum or plasma) greater than 10.2 mg/dL. When the measure was submitted to NQF for maintenance endorsement in 2015, the specifications were updated to include patients in the denominator with missing calcium values. The update was primarily intended to address the absence of a separate measure to monitor monthly measurement of serum or plasma calcium, since the earlier NQF endorsed “measurement of serum calcium concentration” process measure (NQF #0261) was retired in 2011. While the intention was that patients with missing values should be included in both the denominator and numerator of the hypercalcemia measure, this rule was only applied to the denominator. As a result the hypercalcemia measure implemented on DFC in 2016 included patients with missing total uncorrected calcium values (serum or plasma) in the denominator but not in the numerator.

During the 2016 Annual Update period, the numerator details of the measure were subsequently revised to align with the measure's intent. The numerator was revised to include patients with missing calcium values in all three months. Updated NQF submission materials were submitted to NQF on December 20, 2016, and confirmation that the changes were accepted were communicated by NQF on January 12, 2017.

TEP discussion

During the recent Star Rating TEP meeting on February 21, 2017, the TEP members were presented with the information about this update, along with a set of options for adding the measure to the DFC Star Rating. The options, including updating the version of hypercalcemia with the next update of the Star Ratings in October 2018, updating the version of hypercalcemia with the following version of the Star Ratings in October 2019 and a third option to delay the implementation of all new measures, were discussed by the TEP. A strong majority (92%) of the TEP voted to proceed with Option 1 (exact language for voting is included below).

Option 1

Include the updated version of Hypercalcemia in the next update of the Star Rating which will be implemented in October 2018

Issue: Update was not announced during NPC call

Option 2

Do not include the updated version of Hypercalcemia in the 2018 update of the Star Rating, include the revised hypercalcemia in October 2019

Issue: Need to re-baseline star rating two years in a row (2018 and 2019)

Further details about this discussion will be available in the TEP Summary Report for the Star Rating TEP (posted on the CMS website when available).

Next Steps

DFC Star Ratings

CMS presented four candidate measures for the DFC Star Ratings, as well as updated versions of the SMR, SHR, STRR, Fistula, Catheter, and Hypercalcemia measures to be reviewed by the Star Rating TEP. CMS will announce final decisions regarding the inclusion of these measures in the Star Ratings following the conclusion of TEP deliberations.

DFC Public Reporting

New and updated measures will also be available for facilities to preview in the “Dry Run” area of the Preview Report for the October 2017 DFC Update. The Dry Run will allow facilities to preview their data prior to the start of public reporting in the October 2018 DFC Update.

The following new and updated measures will be available to facilities in the Dry Run area of the preview report:

1. Standardized Mortality Ratio (NQF #0369)
2. Standardized Hospitalization Ratio (NQF #1463)
3. Standardized Transfusion Ratio (NQF #2979)
4. Standardized Fistula Rate (NQF# 2977)
5. Long-Term Catheter Rate (NQF# 2978)
6. Hypercalcemia (NQF# 1454)
7. Measurement of nPCR for Pediatric HD Patients (NQF# 1425)

Overall Analysis of the Comments and Recommendations

CMS and UM-KECC appreciate the time dedicated to reviewing and providing comments on the proposed candidate measures for DFC and the DFC Star Ratings.

Public Comment Verbatim Report

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/Actions Taken
January 15, 2017	DFC and Star Rating Measures	See appendix	Andrea Besharat, Manager, Clinical Quality Program & Analytics, DaVita HealthCare Partners	Provider Organization	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
January 15, 2017	DFC and Star Rating Measures	See appendix	Frank Maddux, M.D., Executive Vice President for Clinical & Scientific Affairs, Chief Medical Officer, Fresenius Medical Care (FMC) North America	Provider Organization	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
January 15, 2017	DFC and Star Rating Measures	See appendix	Frank Maddux, M.D., Chairman, Kidney Care Partners (KCP)	Patient Advocacy Organization	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
January 15, 2017	DFC and Star Rating Measures	See appendix	Kerry Willis, PhD, Chief Scientific Officer, National Kidney Foundation (NKF)	Patient Advocacy Organization	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.