Renal Spring 2018 Cycle: CDP Report

DRAFT REPORT FOR CSAC REVIEW

October 23, 2018

NATIONAL QUALITY FORUM

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Renal Spring 2018 Cycle

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Executive Summary

Renal disease is a leading cause of morbidity and mortality in the United States. More than 20 million adults in the United States (10 percent of the population) have chronic kidney disease (CKD). Untreated CKD can result in end-stage renal disease (ESRD) and a host of other health complications. Currently, over half a million people in the United States have received a diagnosis of ESRD, which is the only chronic disease covered by Medicare for people under the age of 65. Considering the high mortality rates and high healthcare utilization and costs associated with ESRD, the need to focus on quality measures for patients with renal disease is particularly important.

For this project, the Standing Committee evaluated two newly submitted measures against NQF's standard evaluation criteria. The Committee did not recommend either measure:

- 3402 Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) (Centers for Medicare and Medicaid Services)
- 3403 Percentage of Prevalent Patients Waitlisted (PPPW) (Centers for Medicare and Medicaid Services)

Brief summaries of the measures reviewed appear in the body of the report; detailed summaries of the Committee's discussion and ratings of the criteria for each measure are in Appendix A.

Introduction

Renal disease is a leading cause of morbidity and mortality in the United States. More than 20 million adults in the United States (10 percent of the population) have chronic kidney disease (CKD), which is associated with premature mortality, decreased quality of life, and increased healthcare costs. Risk factors for CKD include cardiovascular disease, diabetes, hypertension, and obesity.[1] Untreated CKD can result in end-stage renal disease (ESRD). Currently, over half a million people in the United States have received a diagnosis of ESRD.

In 1972, President Richard Nixon signed section 2991 of Public Law 92-603, which established ESRD as the only healthcare condition that Medicare covers for people under the age of 65.[2] Under this provision, people are eligible for Medicare regardless of their age if their kidneys are no longer functioning, if they need regular dialysis, or if they have had a kidney transplant. Considering the high mortality rates and high healthcare utilization and costs associated with ESRD, the need to focus on quality measures for patients with renal disease is particularly important. The United States continues to spend significant resources on care and treatment of CKD and ESRD. In 2010, total Medicare spending rose 6.5 percent, to $522.8 billion, and expenditures for ESRD rose 8 percent, to $32.9 billion.[3]

This project sought to identify and endorse performance measures for accountability and quality improvement that address conditions, treatments, interventions, or procedures relating to kidney disease. On June 18 and 19, 2018, NQF convened a multistakeholder Standing Committee composed of 25 individuals to evaluate two new measures and make recommendations for endorsement.

NQF Portfolio of Performance Measures for Renal Conditions

The Renal Standing Committee (Appendix C) oversees NQF's portfolio of Renal measures (Appendix B). This portfolio contains 21 measures: seven process measures and 14 outcome and resource use measures (see table below).

Table 1. NQF Renal Portfolio of Measures

	Process	Outcome/Resource Use
Dialysis Monitoring	3	2
Hemodialysis	1	3
Hemodialysis Vascular Access	1	2
Patient Safety	—	3
Peritoneal Dialysis	—	4
Other	2	—
Total	7	14

There are additional measures related to renal care, but they are designated as more appropriate for inclusion in other NQF portfolios. These include various diabetes assessment and screening measures, eye care measures, ACEI/ARB medication measures, complications and outcomes measures, cost and resource use measures.

Renal Measure Evaluation

On June 18 and 19, 2018, the Renal Standing Committee evaluated two new measures against NQF's standard evaluation criteria.

Table 2. Renal Measure Evaluation Summary

	Maintenance	New	Total
Measures under consideration	0	2	2
Measures not recommended for endorsement	0	2	2
Reasons for not recommending	Importance – 0 Scientific Acceptability – 0 Use – 0 Overall Suitability – 0 Competing Measure – 0	Importance – 1 Scientific Acceptability – 1 Overall Suitability – 0 Competing Measure – 0	

Comments Received Prior to Committee Evaluation

NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). In addition, NQF solicits comments for a continuous 16-week period during each evaluation cycle via an online tool located on the project webpage. For this evaluation cycle, the commenting period opened on April 24, 2018 and closed on August 22, 2018. As of June 6, four comments were submitted and shared with the Committee prior to the measure evaluation meetings (Appendix E).

Comments Received After Committee Evaluation

Following the Committee's evaluation of the measures under consideration, NQF received 10 comments from seven organizations (including five member organizations) and individuals pertaining to the draft report and to the measures under consideration. All comments for each measure under consideration have been summarized in Appendix A.

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ('support' or 'do not support') for each measure submitted for endorsement consideration to inform the Committee's recommendations. Two NQF member organizations provided their expression of support and did not support the measures.

Summary of Measure Evaluation

The following brief summaries of the measure evaluation highlight the major issues that the Committee considered. Details of the Committee's discussion and ratings of the criteria for each measure are included in Appendix A.

3402 Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) (Centers for Medicare and Medicaid Services): Not Recommended

Description: This measure tracks the number of incident patients at the dialysis facility under the age of 75 listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year of initiating dialysis; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Dialysis Facility; **Data Source**: Claims, Registry Data

This facility-level measure was newly submitted for endorsement. The measure is not yet implemented in a public reporting program, but it has gone through the process of being recommended for Dialysis Facility Compare (DFC), and was scheduled to go through a Dry Run for DFC in July 2018, with the intention of public reporting in October 2019. The Committee agreed that there are substantial gaps and disparities in transplantation rates, and it applauded the developer for working to address this issue. However, Committee members had significant reservations about the measure as specified. Specifically, there were concerns that the evidence submitted by the developer largely related to the links between transplantation and improved patient outcomes, whereas this measure focuses on waitlisting—a step that is further removed from patient outcomes. Committee members also expressed concerns about the validity of the measure, focusing on the potential lack of appropriate exclusions and suggested that there should be a way to account for patient preferences. Some Committee members also noted that transplant communities that perform a relatively high number of preemptive transplants could be achieving the desired outcome, but could score poorly on the measure because these patients would not be included in the denominator. The measure did not pass the Validity criterion and was not recommended for endorsement. The majority of NQF member and public commenters supported the Committee's decision to not endorse this measure. However, one commenter, the Service Employees International Union (SEIU), requested that the Committee reconsider its decision. The Standing Committee agreed that having a transplant measure is very important, but noted that the commenter did not provide any new information that would encourage them to reconsider the measure. The Standing Committee decided to stand by their original recommendation.

3403 Percentage of Prevalent Patients Waitlisted (PPPW) (Centers for Medicare and Medicaid Services): Not Recommended

Description: This measure tracks the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist. Results are averaged across patients prevalent on the last day of each month during the reporting year; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Dialysis Facility; **Data Source**: Claims, Registry Data

This facility-level measure was newly submitted for endorsement. The measure is not yet implemented in a public reporting program, but it has gone through the process of being recommended for Dialysis Facility Compare (DFC), and was scheduled to go through a Dry Run for DFC in July 2018, with the intention of public reporting in October 2019. The Committee expressed similar concerns about this measure as were raised for measure 3402, particularly with regard to the lack of evidence related to the measure focus. The measure did not pass the Evidence criterion and was not recommended for endorsement. The majority of NQF member and public commenters supported the Committee's decision to not endorse this measure. However, one commenter, the Service Employees International

Union (SEIU), requested that the Committee reconsider its decision. The Standing Committee agreed that having a transplant measure is very important, but noted that the commenter did not provide any new information that would encourage them to reconsider the measure. The Standing Committee decided to stand by their original recommendation.

References

[1] U.S. Renal Data System (USRDS). *USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2010. http://www.usrds.org/atlas.htm. Last accessed June 2016.

[2] CROWNWeb. CROWNWeb: History, Purpose, and Usage [video]. http://mycrownweb.org/help/about-crownweb/. Last accessed December 2015.

[3] U.S. Renal Data System (USRDS). *2014 Annual Data Report: Epidemiology of Kidney Disease in the United States*. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2014. http://www.usrds.org/atlas.htm. Last accessed January 2017.

Appendix A: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

Measures Not Recommended

3402 Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)

Submission | Specifications

Description: This measure tracks the number of incident patients at the dialysis facility under the age of 75 listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year of initiating dialysis.

Numerator Statement: Number of patients at the dialysis facility listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year following initiation of dialysis.

Denominator Statement: The denominator for the SWR is the expected number of waitlisting or living donor transplant events at the facility according to each patient's treatment history for patients within the first year following initiation of dialysis, adjusted for age and its functional forms, as well as incident comorbidities, among patients under 75 years of age who were not already waitlisted and did not have first transplantation prior to the initiation of ESRD dialysis.

Exclusions: Exclusions that are implicit in the denominator definition include:

- Patients who were 75 years of age or older at the initiation of dialysis;
- Preemptive patients: patients at the facility who had the first transplantation prior to the start of ESRD treatment; or were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis;
- Patients who were admitted to a hospice at the time of initiation of dialysis;
- Patients who were admitted to a skilled nursing facility (SNF) at incidence or previously according to Form CMS-2728.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Other

Type of Measure: Process

Data Source: Claims, Registry Data

Measure Steward:Centers for Medicare and Medicaid Services

STANDING COMMITTEE MEETING 06/18/2018-06/19/2018

1. Importance to Measure and Report: The measure did not reach consensus on the Importance criteria (1a. Evidence: 1b. Performance Gap)

1a. Evidence: **H-1**; **M-8**; **L-2**; **I-9** 1b. Performance Gap: **H-13**; **M-5**; **L-2**; **I-1**

Rationale:

- The developer provided evidence from the 2011 American Journal of Transplantation Systematic Review: Kidney Transplantation Compared With Dialysis In Clinically Relevant Outcomes. A total

of 110 studies were included in the review, representing over 1.9 million patients. All studies were either retrospective and/or prospective cohort observational study designs. No randomized clinical trials were available for inclusion. Individual studies indicate that kidney transplantation is associated with lower mortality and improved quality of life compared with chronic dialysis treatment.

- The Committee discussed whether the evidence presented by the developer was directly related to the measure focus. Some Committee members suggested that there was evidence highlighting variability in waitlisting rates across dialysis facilities; however, the Committee generally believed that the evidence included in the submission was largely related to the impact of transplantation on patient outcomes and not the impact of waitlisting on patient outcomes. The Committee did not reach consensus on the Evidence criterion.
- After applying all exclusion criteria, the SWR performance score was evaluated for all dialysis facilities that had at least 11 patients and two expected events during 2013-2015. The developer stated the wide variation across facilities suggests there is substantial opportunity for improvement (Mean-1.02; Standard Deviation- 0.81).
- Additionally, the developer provided disparities data for race, sex and ethnicity. The developer stated that there is evidence of significant differences in measure results by sex, race and ethnicity; however, data provided indicated that the adjustment for sex, race and ethnicity generally has very little impact, relative to adjusting for age and incident comorbidities.
- The Committee agreed that there are substantial gaps and disparities in transplantation rates, and applauded the developer for working to address this issue.

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2. Scientific Acceptability of Measure Properties: <u>The measure did not meet the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **H-1**; **M-10**; **L-6**; **I-1** 2b. Validity: **H-0**; **M-5**; **L-14**; **I-0**

<u>Rationale</u>:

- The reliability of the Standardized Waitlist Ratio (SWR) was assessed using data among incident dialysis patients during 2013-2015. The developer estimated inter-unit reliability (IUR) of 0.60 using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by the Analysis of Variance (ANOVA) method.
- The Committee expressed concerns about the ability of the developer to accurately pull data particularly since transplant facilities have varying selection criteria for the waitlist and that the data source may be out of date since waitlist forms tend to change frequently.
- The developer provided face validity and empirical validity of the measure by calculating Spearman correlations. Eight out of the 11 members of the Technical Expert Panel (TEP) supported a dialysis facility measure related to waitlisting. The developer stated the Spearman correlation coefficient between facility SWR and Standardized Transplant Ratio (STR) demonstrated highly significant correlation with a rho of 0.52 and p of <.001. The SWR was negatively correlated with First Year Standardized Mortality Ratio in 2013-2015 with a rho of -0.19 and p of <.001.
- Committee members also expressed concerns about the validity of the measure, focusing on the potential lack of appropriate exclusions and suggesting that there should be a way to account for patient preferences. The Committee was particularly concerned that the measure does not account for patient choice or preference, noting that some patients express a clear desire to not undergo a transplant. The developer noted that education and preparation about various

options can change patients' minds about transplantation, and suggested that this is an area where dialysis facilities could improve their performance.
- Some Committee members expressed concern about the effect of preemptive transplants on facility performance on this measure. It was noted that well-organized transplant communities that are performing a higher-than-average number of preemptive transplants could be achieving the desired outcome, but could perform poorly on this measure because those patients would never be counted in the denominator population.
- Some Committee members also expressed concern that the measure could have the unintended consequence of incentivizing referral of patients who are not suitable candidates for transplantation.
- The developer noted that the goal of this measure is not to get every patient waitlisted, but to get every appropriate patient waitlisted.
- The developer also clarified the intent of the measure, which is to assess waitlisting rather than referral because there are a number of other steps besides referrals that can and should be taken to help patients successfully be waitlisted, and that this measure is intended to promote shared accountability in reducing disparities in kidney transplant rates.
- Ultimately, the Committee determined that without additional exclusions, this measure would not achieve the desired result; the measure did not pass the validity criterion.

3403 Percentage of Prevalent Patients Waitlisted (PPPW)

Submission | Specifications

Description: This measure tracks the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist. Results are averaged across patients prevalent on the last day of each month during the reporting year.

Numerator Statement: Number of patient months in which the patient at the dialysis facility is on the kidney or kidney-pancreas transplant waitlist as of the last day of each month during the reporting year.

Denominator Statement: All patient-months for patients who are under the age of 75 in the reporting month and who are assigned to the dialysis facility according to each patient's treatment history as of the last day of each month during the reporting year.

Exclusions: Exclusions that are implicit in the denominator include:

- Patients who were at age 75 or older in the reporting month.
- Patient who were admitted to a skilled nursing facility (SNF) or a hospice during the month of evaluation were excluded from that month; patients who were admitted to a skilled nursing facility (SNF) at incidence or previously according to Form CMS-2728 were also excluded.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Other

Type of Measure: Process

Data Source: Claims, Registry Data

Measure Steward: Centers for Medicare and Medicaid Services

STANDING COMMITTEE MEETING 06/19/2018

1. Importance to Measure and Report: The measure did not meet the Importance criteria

(1a. Evidence: 1b. Performance Gap)

1a. Evidence: **H-1**; **M-4**; **L-2**; **I-11**

Rationale:

- The developer provided evidence from the 2011 American Journal of Transplantation Systematic Review: Kidney Transplantation Compared With Dialysis In Clinically Relevant Outcomes. A total of 110 studies were included in the review, representing over 1.9 million patients. All studies were either retrospective and/or prospective cohort observational study designs. No randomized clinical trials were available for inclusion. Individual studies indicate that kidney transplantation is associated with lower mortality and improved quality of life compared with chronic dialysis treatment.
- Similar to the discussion on measure #3402, Committee members expressed concern that the evidence presented was primarily related to the impact of transplantation on patient outcomes, rather than the impact of waitlisting on patient outcomes, and therefore was not directly relevant to the measure focus. The measure did not pass the Evidence criterion.

Appendix B: Renal Portfolio—Use in Federal Programs

Based on information provided in the CMS Inventory Tool

NQF #	Title	Federal Programs: Finalized as of July 3, 2018
0249	Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy--Minimum Delivered Hemodialysis Dose	End-Stage Renal Disease Quality Incentive Program
0256	Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access	End-Stage Renal Disease Quality Incentive Program
0257	Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)	End-Stage Renal Disease Quality Incentive Program
0318	Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum	End-Stage Renal Disease Quality Incentive Program
0369	Dialysis Facility Risk-adjusted Standardized Mortality Ratio	End-Stage Renal Disease Quality Incentive Program
1423	Minimum spKt/V for Pediatric Hemodialysis Patients	End-Stage Renal Disease Quality Incentive Program
1454	Proportion of patients with hypercalcemia	End-Stage Renal Disease Quality Incentive Program
1463	Standardized Hospitalization Ratio for Admissions	End-Stage Renal Disease Quality Incentive Program
1667	Pediatric Kidney Disease : ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL	Merit-Based Incentive Payment System (MIPS)
2977	Hemodialysis Vascular Access: Standardized Fistula Rate	End-Stage Renal Disease Quality Incentive Program
2978	Hemodialysis Vascular Access: Long-term Catheter Rate	End-Stage Renal Disease Quality Incentive Program
2979	Standardized Transfusion Ratio for Dialysis Facilities	End-Stage Renal Disease Quality Incentive Program

Appendix C: Renal Standing Committee and NQF Staff

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Appendix D: Measure Specifications

3402 Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)

STEWARD

Centers for Medicare and Medicaid Services

DESCRIPTION

This measure tracks the number of incident patients at the dialysis facility under the age of 75 listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year of initiating dialysis.

TYPE

Process

DATA SOURCE

Claims, Registry Data CROWNWeb (including CMS Medical Evidence Form (Form CMS-2728)) is the primary data source used for placing patients at dialysis facilities, age and incident comorbidities adjustments and exclusion of patients => 75 year-old (see information provided under "denominator details"). Organ Procurement and Transplant Network (OPTN) is the data source for waitlist or living donor transplant events. The Nursing Home Minimum Dataset and the CMS Medical Evidence Form (Form CMS-2728) are used to identify SNF patients. A separate CMS file that contains final action claims submitted by Hospice providers was used to determine the hospice status.

LEVEL

Facility

SETTING

Other Dialysis Facility

NUMERATOR STATEMENT

Number of patients at the dialysis facility listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year following initiation of dialysis.

NUMERATOR DETAILS

The numerator for the SWR is the observed number of events (i.e., waitlisting or receipt of a living-donor transplant). To be included in the numerator for a particular facility, the patient must meet one of the two criteria within one year follow-up time period since their first ESRD service date:

- The patient is on the kidney or kidney-pancreas transplant waitlist or
- The patient has received a living donor transplant

DENOMINATOR STATEMENT

The denominator for the SWR is the expected number of waitlisting or living donor transplant events at the facility according to each patient's treatment history for patients within the first year following initiation of dialysis, adjusted for age and its functional forms, as well as incident comorbidities, among patients under 75 years of age who were not already waitlisted and did not have first transplantation prior to the initiation of ESRD dialysis.

DENOMINATOR DETAILS

CROWNWeb is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source. Information regarding first ESRD service date, death, age and incident comorbidities adjustments and transplant is obtained from CROWNWeb (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN) and the Social Security Death Master File.

The denominator of the SWR for a given facility represents the number of expected events (waitlistings or living-donor transplants) at the facility. The estimation of this expected number accounts for the follow-up time and risk profile of each patient. The risk profile is quantified through covariate effects estimated through Cox regression (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994).

The model is currently adjusted for age and incident comorbidities.

EXCLUSIONS

Exclusions that are implicit in the denominator definition include:

- Patients who were 75 years of age or older at the initiation of dialysis;
- Preemptive patients: patients at the facility who had the first transplantation prior to the start of ESRD treatment; or were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis;
- Patients who were admitted to a hospice at the time of initiation of dialysis;
- Patients who were admitted to a skilled nursing facility (SNF) at incidence or previously according to Form CMS-2728.

EXCLUSION DETAILS

The CMS Medical Evidence Form and the CMS Long Term Care Minimum Data Set (MDS) were the data sources used for determining skilled nursing facility (SNF) patients. Patients who were identified in Questions 17u and 22 on the CMS Medical Evidence Form as institutionalized and SNF/Long Term Care Facility, respectively, or who had evidence of admission to a skilled nursing facility based on the MDS before their first service date and were not discharged prior to initiation of dialysis were identified as SNF patients. For hospice patients, a separate CMS file that contains final action claims submitted by Hospice providers was used to determine the hospice status.

RISK ADJUSTMENT

Statistical risk model

STRATIFICATION

N/A

TYPE SCORE

Ratio better quality = higher score

ALGORITHM

See flowchart in Appendix.

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None

3403 Percentage of Prevalent Patients Waitlisted (PPPW)

STEWARD

Centers for Medicare and Medicaid Services

DESCRIPTION

This measure tracks the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist. Results are averaged across patients prevalent on the last day of each month during the reporting year.

TYPE

Process

DATA SOURCE

Claims, Registry Data CROWNWeb is the primary data source we used for denominator, risk adjustment (age) and exclusion of patients at 75 year-old or older (see information provided under "denominator details"). Organ Procurement and Transplant Network (OPTN) is the data source for numerator (waitlisting). The Nursing Home Minimum Dataset and Questions 17u and 22 on the CMS Medical Evidence Form are used to identify SNF patients. A separate CMS file that contains final action claims submitted by Hospice providers was used to determine the hospice status.

LEVEL

Facility

SETTING

Other Dialysis Facility

NUMERATOR STATEMENT

Number of patient months in which the patient at the dialysis facility is on the kidney or kidney-pancreas transplant waitlist as of the last day of each month during the reporting year.

NUMERATOR DETAILS

To be included in the numerator for a particular month, the patient must be on the kidney or kidney-pancreas transplant waitlist as of the last day of the month during the reporting year.

DENOMINATOR STATEMENT

All patient-months for patients who are under the age of 75 in the reporting month and who are assigned to the dialysis facility according to each patient's treatment history as of the last day of each month during the reporting year.

DENOMINATOR DETAILS

A treatment history file is the data source for the denominator calculation used for the analyses supporting this submission. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility.

CROWNWeb is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source. Information regarding first ESRD service date, death, waitlist status and transplant is obtained from CROWNWeb (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN) and the Social Security Death Master File. For denominator exclusions, the Nursing Home Minimum Dataset and the Questions 17u and 22 on CMS Medical Evidence Form are used to identify patients in skilled nursing facilities. Additionally, a separate CMS file that contains final action claims submitted by Hospice providers was used to determine the hospice status.

The model is currently age-adjusted, with age updated each month.

EXCLUSIONS

Exclusions that are implicit in the denominator include:

• Patients who were at age 75 or older in the reporting month.

• Patient who were admitted to a skilled nursing facility (SNF) or a hospice during the month of evaluation were excluded from that month; patients who were admitted to a skilled nursing facility (SNF) at incidence or previously according to Form CMS-2728 were also excluded.

EXCLUSION DETAILS

The Nursing Home Minimum Dataset and the Questions 17u and 22 on CMS Medical Evidence Form are used to identify patients in skilled nursing facilities. For hospice patients, a separate CMS file that contains final action claims submitted by Hospice providers was used to determine the hospice status.

RISK ADJUSTMENT

Statistical risk model

STRATIFICATION

N/A

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

See flowchart in Appendix.

None

Appendix E: Pre-Evaluation Comments

Comments received as of June 6, 2018.

3402 Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)

Submitted by National Kidney Foundation

The National Kidney Foundation appreciates the intent of this measure to ensure that patients are waitlisted as early as possible after starting dialysis, if they were not already waitlisted. However, we are concerned this measure is limited in terms of actionability by the dialysis center as the ultimate decision on waitlist status is made by the transplant center and the patient. Dialysis facilities have a role in educating patients about transplant and supporting their active listing. However, incident dialysis patients, who were not listed before starting dialysis, may be more complex and have comorbidities that make them ineligible for the waitlist during the first year. While it is the responsibility of the dialysis facility to work to improve the health and functional status of dialysis patients during the first year, much of the final decision is beyond their control. In addition, dialysis units involved in education and care coordination in the transition of advanced chronic kidney disease to end-stage renal disease would not be recognized for pre-emptively having patients on the waitlist. To better improve earlier wait listing, the National Kidney Foundation instead encouraged the Centers for Medicare & Medicaid Services to explore measure development to evaluate transplant referrals and patient education within the first 12 months of initiating dialysis.

3403 Percentage of Prevalent Patients Waitlisted (PPPW)

Submitted by National Kidney Foundation

The National Kidney Foundation supports this measure as it is very meaningful for patients. This measure would incentivize greater care coordination by the dialysis facility with the transplant center. Many transplant centers have dialysis outreach programs to better educate facility staff and patients about the transplant process and the patient and dialysis facility role in the process. However, gaps in patients getting waitlisted remain. Patients continue to report that they were not fully informed about transplant or were provided misinformation that led them not to not pursue transplant. Holding dialysis facilities accountable for ensuring their patient population is knowledgeable about transplant and supporting patients to maintain their status on the waitlist will help address this current gap in care. Dialysis facilities can help support patients in maintaining their active status on the waitlist for routine antibody and other periodic testing.

However, ultimately, the decision on whether a patient is listed for a transplant is made by the transplant center that evaluated the patient (and the patient's desire for a transplant). These are complex decisions that consider many factors and vary by transplant center and geographic region, which would make nationwide comparisons of waitlist percentages difficult to interpret. The effect of this variance in transplantation policy on dialysis facility performance on this measure should be considered prior to implementation.

3402 Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)

Submitted by Kidney Care Partners

KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution to dialysis facilities of successful/unsuccessful waitlisting. KCP believes that while a referral to a transplant center, initiation of the waitlist evaluation process, or completion of the waitlist evaluation process may be appropriate facility-level measures that could be used in ESRD quality programs, the Percentage of Prevalent Patients Waitlisted (PPPW) and Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) are not. Waitlisting per se is a decision made by the transplant center and is beyond a dialysis facility's locus of control. In reviewing the SWR, we offer the following comments:[1]

FACILITY ATTRIBUTION. KCP appreciated the Measure Applications Partnership (MAP) Hospital Workgroup's recommendation that the Waitlist measures also be reviewed by NQF's Attribution Expert Panel to assess KCP's and other stakeholders' concerns about the measures' attribution models. However, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to dialysis facilities and believe this is a fatal structural flaw. The transplant center decides whether a patient is placed on a waitlist, not the dialysis facility. One KCP member who is a transplant recipient noted there were many obstacles and delays in the evaluation process with multiple parties that had nothing to do with the dialysis facility—e.g., his private pay insurance changed the locations where he could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a facility each month through the PPPW and SWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle", which states that measures' attribution models should fairly and accurately assign accountability.[2] KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued.

AGE AS THE ONLY SOCIODEMOGRAPHIC RISK VARIABLE. KCP appreciated the MAP Workgroup's recommendation that the Waitlist measures also be reviewed by NQF's Disparities Standing Committee to assess KCP's and other stakeholders' concerns about the measures' risk of potentiating existing health inequities. KCP strongly believes age as the only sociodemographic risk variable is insufficient. We believe other biological and demographic variables are important, and not accounting for them is a significant threat to the validity of both measures. Transplant centers assess a myriad of demographic factors—e.g., family support, ability to adhere to medication regimens, capacity for follow-up, insurance-related issues, etc. Given transplant centers consider these types of sociodemographic factors, any waitlisting measure risk model should adjust for them. Of note, like the Access to Kidney Transplantation TEP, KCP does not support adjustment for waitlisting based on economic factors or by race or ethnicity.

Geography, for instance, should be examined, since regional variation in transplantation access is significant. Waitlist times differ regionally, which will ultimately change the percentage of patients on the waitlist and impact performance measure scores. That is, facilities in a region with long wait times

will "look" better than those in a region with shorter wait times where patients come off the list more rapidly—even if both are referring at the same rate.

Additionally, criteria indicating a patient is "not eligible" for transplantation can differ by location—one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply them differently or have additional/ different criteria. The degree to which these biological factors influence waitlist placement must be accounted for in any model for the measure to be a valid representation of waitlisting.

HOSPICE EXCLUSION. We note that an exclusion for patients admitted to hospice during the month of evaluation has been incorporated into both measures. KCP agrees that the transplantation access measures should not apply to persons with a limited life expectancy and so is pleased to see this revision.

RISK MODEL FIT. KCP appreciates the MAP Hospital Workgroup's recommendation that the Waitlist measures also be reviewed by NQF's Scientific Methods Panel to assess KCP's and other stakeholders' concerns about the measures' risk models. We note that risk model testing yielded an overall C-statistic of 0.72 for the PPPW and 0.67 for the SWR, raising concerns that the models will not adequately discriminate performance. Smaller units, in particular, might look worse than their actual performance. We reiterate our long-held position that a minimum C-statistic of 0.8 is a more appropriate indicator of a model's goodness of fit, predictive ability, and validity to represent meaningful differences among facilities.

STRATIFICATION OF RELIABILITY RESULTS BY FACILITY SIZE. CMS has provided no stratification of reliability scores by facility size for either measure; we are thus unable to discern how widely reliability varies across the spectrum of facility sizes. We are concerned that the reliability for small facilities might be substantially lower than the overall IURs, as has been the case, for instance, with other CMS standardized ratio measures. This is of particular concern with the SWR, for which empiric testing has yielded an overall IUR of only 0.6—interpreted as "moderate" reliability by statistical convention.[3] To illustrate our concern, the Standardized Transfusion Ratio for Dialysis Facilities (STrR) measure (NQF 2979) also was found to have an overall IUR of 0.60; however, the IUR was only 0.3 ("poor" reliability) for small facilities (defined by CMS as <=46 patients for the STrR).

Without evidence to the contrary, KCP is thus concerned that SWR reliability is similarly lower for small facilities, effectively rendering the metric meaningless for use in performance measurement in this group of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all facilities by providing data by facility size.

MEANINGFUL DIFFERENCES IN PERFORMANCE. We note that with large sample sizes, as here, even statistically significant differences in performance may not be clinically meaningful. A detailed description of measure scores, such as distribution by quartile, mean, median, standard deviation, outliers, should be provided to allow stakeholders to assess the measure and allow for a thorough review of the measures' performance.

ADDITIONAL LANGUAGE RELATED TO EXCLUSIONS. We note that since KCP reviewed these measures and provided comment to CMS in 2016, one PPW exclusion has been altered with the following boldface text: Patients admitted to a skilled nursing facility or hospice during the month of evaluation are excluded from that month; patients admitted to a skilled nursing facility at incidence or previously according to Form CMS 2728 are also excluded. Similarly, one SWR exclusion has been altered with the following boldface/strikeout text: Preemptive patients: Patients at the facility who had the first transplantation prior to the start of ESRD treatment orPatients at the facility whowere listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis.

KCP supports these changes, but notes that the testing forms submitted by the developer do not provide information on the impact of these exclusions on performance, as required by NQF. We recommend the appropriate, required testing be reported.

INCIDENT COMORBIDITIES INCORPORATED INTO RISK MODEL. We note that eleven incident comorbidities—heart disease, inability to ambulate, inability to transfer, COPD, malignant neoplasm/cancer, PVD, CVD, alcohol dependence, drug dependence, amputation, and needs assistance with daily activities—have been incorporated into the SWR risk model. All are collected through the CMS Form 2728. As we have noted before, we continue to be concerned about the validity of the 2728 as a data source and urge CMS to work with the community to assess this matter.

RATE VS. RATIO. Notwithstanding our many concerns regarding attribution and risk adjustment of this measure, consistent with our comments on other standardized ratio measures (e.g., SHR, SMR), KCP prefers normalized rates or year-over-year improvement in rates instead of a standardized ratio. We believe comprehension, transparency, and utility to all stakeholders is superior with a scientifically valid rate methodology.

In sum and for the reasons stated above, KCP does not believe that the SWR measure is appropriate for NQF endorsement.

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PROCESS VS. INTERMEDIATE OUTCOME MEASURE. The Measure Submission Form identified the PPPW as a process measure. KCP believes the PPPW is an intermediate outcome measure and recommends it be indicated as such.

In sum and for the reasons stated above, KCP does not believe that the PPPW measure is appropriate for NQF endorsement.

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