NATIONAL QUALITY FORUM

Memo

October 23, 2018

To: Consensus Standards Approval Committee (CSAC)

From: Renal Project Team

Re: Renal Spring 2018 Review Cycle

CSAC Action Required

The CSAC will review recommendations from the Renal project at its October 23, 2018 meeting and vote on whether to uphold the recommendations from the Standing Committee.

This memo includes a summary of the project, measure recommendations, themes identified and responses to the public and member comments and the results from the NQF member expression of support. The following documents accompany this memo:

1. **Renal Draft Report**. The draft report has been updated to reflect the changes made following the Standing Committee's discussion of public and member comments. The complete draft report and supplemental materials are available on the project webpage.
2. **Comment Table**. Staff has identified themes within the comments received. This table lists 10 comments received during the post-meeting comment period and the NQF and Standing Committee responses.

Background

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. 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.

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. The Committee did not recommend either measure.

Draft Report

The Renal Spring 2018 draft report presents the results of the evaluation of two measures considered under the Consensus Development Process (CDP). Both measures were not recommended.

The measures were evaluated against the 2017 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures under consideration	0	2	2
Measures not recommended for endorsement	0	2	2
Reasons for not recommending		Importance - 1 Scientific Acceptability - 1	

Measures Not Recommended for Endorsement

(See Appendix B for the Committee's votes and rationale)

- 3402: Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) (CMS)
- 3403: Percentage of Prevalent Patients Waitlisted (PPPW) (CMS)

Comments and Their Disposition

NQF received 10 comments from seven organizations (including five member organizations) and individuals pertaining to the draft report and to the measures under consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the Renal project webpage.

Comment Themes and Committee Responses

The Standing Committee reviewed all of the submitted comments (general and measure specific). Committee members focused their discussion on measures with the most significant and recurring issues.

Reconsideration of 3402: Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) and 3403: Percentage of Prevalent Patients Waitlisted (PPPW):

The majority of the commenters supported the Committee's decision to not recommend the two measures under review for endorsement. However, one commenter, the Service Employees International Union (SEIU), requested that the Committee reconsider its decision based on the following:

- The measures focusing on the waitlisting process are appropriate for improving access to kidney transplantation, especially given that dialysis facilities exert substantial control over an important set of activities that are related to waitlisting, starting with proper education of dialysis patients about the option for transplant, to referral of appropriate patients to a transplant center for evaluation, assisting patients with completion of the transplant evaluation process, and optimizing the health and functional status of patients in order to increase the patient's candidacy for transplant waitlisting. The waitlisting measures have high public value as they will provide transparency on which dialysis facilities are doing a

better job at successfully assisting appropriate patients to be placed on the transplant waitlist.

- Sufficient evidence and appropriate rationale was provided to meet the Evidence criterion for both of the renal measures. The evidence demonstrates that the earlier a renal patient has access to transplantation, especially after starting dialysis, the better their chance for long-term survival, and that there is a wide variation in transplant waitlisting rates among dialysis facilities. Clearly there is a need for these transplant waitlisting measures in order to improve facility performance and ensure that appropriate renal patients are supported in the process to be placed on the transplant waitlist.
- A referral-based measure would not be sufficient. Given their important role in the process leading to waitlisting, there is a need for a more comprehensive measure to ensure that dialysis facilities are doing more than simply referring patients, but actually taking active steps to ensure that patients complete the transplant evaluation process, and that the health and functional status of patients are sufficient to support their candidacy for the transplant waitlist.
- The variance in transplant waitlisting is extremely troubling and ought to be addressed as soon as possible, especially in order to limit healthcare disparities for people of color.

Committee Response

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 measures. The Standing Committee decided to stand by their original recommendation.

Member Expression of Support

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. Appendix C details the expression of support.

Appendix A: CSAC Checklist

The table below lists the key considerations to inform the CSAC's review of the measures submitted for endorsement consideration.

Key Consideration	Yes/No	Notes
Were there any process concerns raised during the CDP project? If so, briefly explain.	No	
Did the Standing Committee receive requests for reconsideration? If so, briefly explain.	No	
Did the Standing Committee overturn any of the Scientific Methods Panel's ratings of Scientific Acceptability? If so, state the measure and why the measure was overturned.	No	While both measures were reviewed by the Methods Panel, the Committee did not pass measure #3402 on validity because of concerns with exclusions and other clinical aspects related to validity. (The Committee did not pass measure #3403 on evidence.)
If a recommended measure is a related and/or competing measure, was a rationale provided for the Standing Committee's recommendation? If not, briefly explain.	N/A	
Were any measurement gap areas addressed? If so, identify the areas.	No	
Are there additional concerns that require CSAC discussion? If so, briefly explain.	No	

Appendix B: Measures Not Recommended for Endorsement

The table below lists the Committee's vote and rationale for measures not recommended for endorsement.

Legend: H = High; M = Moderate; L = Low; I = Insufficient

Measure	Voting Results	Standing Committee Rationale
3402 Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) (CMS)	**Evidence** H-1**;** M-8**;** L-2**;** I-9 **Gap** H-13; M-5; L-2; I-1 **Reliability** H-1; M-10; L-6; I-1 **Validity** H-0; M-5; L-14; I-0	• 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 – not the impact of waitlisting on patient outcomes. The Committee did not reach consensus on the Evidence criterion. • 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. Ultimately, the Committee was not able to reach consensus on the reliability of the measure. • Committee members 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 mind 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

Measure	Voting Results	Standing Committee Rationale
		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 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) (CMS)	**Evidence** H-1; M-4; L-2; I-11	• 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 C: NQF Member Expression of Support Results

Two NQF member organizations provided their expressions of support. None of the two measures under consideration received support from NQF members. Results for each measure are provided below.

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

Member Council	Support	Do Not Support	Total
QMRI	0	1	1

3403: Percentage of Prevalent Patients Waitlisted (PPPW) (CMS)

Member Council	Support	Do Not Support	Total
Consumer	0	1	1
QMRI	0	1	1

Appendix D: 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.

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6 . Public and Member Comment

The majority of the commenters supported the Committee's decision to not endorse the two measures under review. However, one commenter, the Service Employees International Union (SEIU), requested that the Committee reconsider its decision based on the following:

- The measures focusing on the waitlisting process are appropriate for improving access to kidney transplantation, especially given that dialysis facilities exert substantial control over an important set of activities that are related to waitlisting, starting with proper education of dialysis patients about the option for transplant, to referral of appropriate patients to a transplant center for evaluation, assisting patients with completion of the transplant evaluation process, and optimizing the health and functional status of patients in order to increase the patient's candidacy for transplant waitlisting. The waitlisting measures have high public value as they will provide transparency on which dialysis facilities are doing a better job at successfully assisting appropriate patients to be placed on the transplant waitlist.

- Sufficient evidence and appropriate rationale was provided to meet the Evidence criterion for both of the renal measures. The evidence demonstrates that the earlier a renal patient has access to transplantation, especially after starting dialysis, the better their chance for long-term survival, and that there is a wide variation in transplant waitlisting rates among dialysis facilities. Clearly there is a need for these transplant waitlisting measures in order to improve facility performance and ensure that appropriate renal patients are supported in the process to be placed on the transplant waitlist.
- A referral-based measure would not be sufficient. Given their important role in the process leading to waitlisting, there is a need for a more comprehensive measure to ensure that dialysis facilities are doing more than simply referring patients, but actually taking active steps to ensure that patients complete the transplant evaluation process, and that the health and functional status of patients are sufficient to support their candidacy for the transplant waitlist.
- The variance in transplant waitlisting is extremely troubling and ought to be addressed as soon as possible, especially in order to limit healthcare disparities for people of color.

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 measures. The Standing Committee decided to stand by their original recommendation.

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.

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waitlisting measures in order to improve facility performance and ensure that appropriate renal patients are supported in the process to be placed on the transplant waitlist.

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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 measures. The Standing Committee decided to stand by their original recommendation.