NATIONAL QUALITY FORUM

Memo

March 12, 2019

To: Consensus Standards Approval Committee (CSAC)

From: Renal Project Team

Re: Renal Spring 2018/Fall 2018 Review Cycles and Reconsideration Requests

CSAC Action Required

The CSAC will review recommendations from the Renal Standing Committee at its March 12, 2019 meeting and vote on whether to uphold the Committee's recommendations.

This memo includes a summary of the current Renal project and a summary of recommendations on measures 3402 (Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients) and 3403 (Percentage of Prevalent Patients Waitlisted), which, at the request of CSAC, were reviewed by a Renal Transplant Technical Expert Panel (TEP) that provided input to the Standing Committee on the potential invocation of an exception to NQF's Evidence criterion. The following document accompanies this memo:

1. **Renal Draft Report**. The draft report has been updated to reflect the Standing Committee's discussion of the TEP's input and the Committee's reconsideration of the Evidence criterion for these measures. The complete draft report and supplemental materials are available on the project webpage.

Background

The NQF Renal Standing Committee decided not to recommend two measures for endorsement during the spring 2018 review cycle:

- 3402 Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) (CMS)
    - The Committee did not reach consensus on the Evidence criterion for this measure; the measure was ultimately not recommended because it did not pass the Validity criterion.
- 3403 Percentage of Prevalent Patients Waitlisted (PPPW) (CMS)
    - This measure did not pass the Evidence criterion, and so was not recommended for endorsement.

The University of Michigan–Kidney Epidemiology and Cost Center (UM-KECC), the developer of the two measures, submitted a request for reconsideration to the CSAC chairs. In support of the reconsideration request, the developer claimed that:

- NQF's measure evaluation criteria, specifically the evidence algorithm for process measures, is flawed, and does not allow important measures with limited evidence to meet the criterion.

- There are concerns about the Renal Standing Committee's perceived impartiality and the lack of broader representation from patients/patient advocates and the transplant provider community.

The CSAC reviewed UM-KECC's reconsideration request during their October 23-24, 2018 in-person meeting and determined there were grounds for a reconsideration, and requested the Renal Standing Committee re-review both measures against the Evidence criterion, with a particular focus on the question of whether an exception to that criterion was warranted.

In response to the concern raised about the composition of the Committee, the CSAC requested that NQF form a Temporary Technical Expert Panel (TEP) with the following additional expertise for the re-evaluation of the measures:

- Dialysis patient who is waiting for a kidney transplant
- Disparities and health equity.

The Renal Transplant TEP met on January 8, 2019 to evaluate the evidence for measures 3402 and 3403 (see the TEP roster in Appendix A) and recommended that both measures pass the evidence criterion with an exception. The Renal Standing Committee held measure evaluation web meetings on January 30 and 31, during which the Committee reviewed the TEP's findings and subsequently re-voted on the Evidence criterion for measures 3402 and 3403. Since the evidence for the two measures was almost identical, the Committee voted on the Evidence criterion for both measures simultaneously.

Draft Report

The Renal spring 2018/sall 2018 draft report presents evaluation results of both measures, including the re-evaluation that came as a result of the reconsideration request. Ultimately, the Standing Committee did not recommend either measure for NQF endorsement.

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 - 2	

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)

Appendix A: Renal Transplant Technical Expert Panel (TEP)

Donnie Anderson
Board of Directors Member, Dialysis Patient Citizens
Kalamazoo, Michigan

Donnie Anderson has been a dialysis patient for more than 20 years. He has been active in advocacy for the past five years, including one year on the DPC Board. Donnie has had two previous transplants and is currently waitlisted in Michigan for a third. Donnie has a hereditary form of kidney disease, which is shared with several other family members. This is what spurred his involvement in the kidney community.

Michelle Cabrera
Director, Health Policy and Research, SEIU California
Washington, District of Columbia

Michelle Doty Cabrera directs healthcare policy development on behalf of 700,000 workers. Prior to joining SEIU, Cabrera was a program officer in the California Health Care Foundation where she led the foundation's policy strategy and outreach. From 2005-2010 Cabrera was a health and human services analyst with the California legislature responsible for policy development, analysis, and oversight in health and human services matters. Cabrera received a bachelor of science degree in international politics from Georgetown University and a certificate in community economic development from San Diego State University.

Appendix B: Measures Not Recommended for Endorsement

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

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

Measure	Standing Committee Voting Results (from January 2019 Measure Evaluation Discussion)	Renal Transplant TEP Rationale	Standing Committee Rationale

3402 Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) (CMS)
 	
AND
 	
3403 Percentage of Prevalent Patients Waitlisted (PPPW) (CMS)
	Evidence
	H-0; M-3; L-5; I-10
		• *Is the provided body of evidence directly relevant to measured healthcare process?*
		  • The TEP agreed that the body of evidence provided for both measures was not directly relevant to the measured healthcare process.
		• *Are there or could there be performance measures of a related health outcome, OR evidence-based intermediate clinical outcome or process?*
		  • The TEP members stated that they would prefer a waitlisting measure over a referral or transplant measure. They suggested that a referral measure may not be impactful enough and that providers need to be held responsible for their part in getting patients on the waitlist. Donnie Anderson, a kidney transplant recipient who is on the waitlist for a second transplant, stated that the waitlisting process can sometimes be confusing, and providers should be motivated to help prospective kidney transplant candidates navigate the system.
			• *Is the provided body of evidence directly relevant to measured healthcare process?*
			  • 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.
			• *Are there or could there be performance measures of a related health outcome, OR evidence-based intermediate clinical outcome or process?*
			  • The Standing Committee noted that there may be other performance measures that would more accurately reflect provider performance in this area, specifically a transplant measure since there currently is already a mechanism to track waitlist rates and transplant rates through the Dialysis Facility Reports.

Measure	Standing Committee Voting Results (from January 2019 Measure Evaluation Discussion)	Renal Transplant TEP Rationale	Standing Committee Rationale

		• *Is there evidence of a systematic assessment of expert opinion that the benefits of what is being measured outweigh potential harms?*
		  • While the TEP members could not cite evidence that the measure's potential benefits outweighed the potential harm, they did agree that this measure would be far more beneficial than harmful to eligible patients in need of a transplant.
		• *Do you agree that it is OK (or beneficial) to hold providers accountable for performance in the absence of empirical evidence of benefits to patients?*
		  • The TEP agreed that providers should be held accountable and that the measure might encourage providers to take a more active role in getting patients on waitlists.
			• *Is there evidence of a systematic assessment of expert opinion that the benefits of what is being measured outweigh potential harms?*
			  • The Standing Committee agreed with the TEP that, in theory, the potential benefits may not outweigh the potential harm, but the question asked for evidence of a systematic assessment of expert opinion, which was not provided. The developer stated that the face validity presented in the validity section could be seen as evidence of a systematic assessment of expert opinion. However, the developer's TEP did not address the specific question of benefits vs. harms of the measure.
			• *Do you agree that it is OK (or beneficial) to hold providers accountable for performance in the absence of empirical evidence of benefits to patients?*
			  • The Standing Committee determined that it would not be appropriate to hold providers accountable for performance on this measure in the absence of direct empirical evidence of benefit to patients.

Appendix C: 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

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

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1. Importance to Measure and Report: <u>The Committee did not reach consensus on the Importance criteria</u>

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

1a. Evidence: **H-0; M-3; L-5; I-10**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: The measure did not meet the Scientific Acceptability criteria

(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**

Rationale:

- 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.

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.

Consensus Standards Approval Committee (CSAC) Review 10/23/2018 – 10/24/2018

The CSAC discussed the Renal Standing Committee's recommendations during its October 23-24 in-person meeting and reviewed the developer's request for reconsideration. CSAC members noted the importance of improving transplant rates for dialysis patients, particularly given disparities in care in this area. To ensure that the developer's concerns were fully considered and addressed, the CSAC requested that NQF form a temporary Renal Transplant Technical Expert Panel to supplement the perspective of the Renal Standing Committee and provide input to the Standing Committee on evaluation of the evidence supporting these measures.

Technical Expert Panel (TEP) Review 1/8/2019

NQF convened a TEP to provide input to the Renal Standing Committee on the question of whether the measures should be granted an exception to NQF's Evidence criterion. The TEP recommended that the measure pass evidence with an exception based on the following rationale:

- The TEP agreed that the body of evidence provided for both measures was not directly relevant to the measured healthcare process.
- The TEP members stated that they preferred a waitlisting measure over a referral or transplant measure. They expressed that a referral measure would not be impactful enough and that providers need to be held responsible for their part in getting patients

on the waitlist. Donnie Anderson, a kidney transplant recipient who is on the waitlist for a second transplant, stated that the waitlisting process can sometimes be confusing, and providers should be motivated to help prospective kidney transplant candidates navigate the system.

- While the TEP members could not cite evidence that the measure's potential benefits outweighed the potential harm, they did agree that this measure would be far more beneficial than harmful to eligible patients in need of a transplant.
- The TEP agreed that providers should be held accountable and that the measure might encourage providers to take a more active role in getting patients on waitlists.

Standing Committee Reconsideration 1/30/2019 – 1/31/2019

The Renal Standing Committee convened on January 30, 2019, to review and discuss the TEP's recommendations, and to re-vote on the Evidence criteria in light of that input. Ultimately, the Standing Committee did not pass either measure on the Evidence criterion. The Committee provided the following rationale for their decision:

- 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 Standing Committee noted that there may be other performance measures that would more accurately reflect provider performance in this area, specifically a transplant measure since there currently is already a mechanism to track waitlist rates and transplant rates through the Dialysis Facility Reports.
- The Standing Committee agreed with the TEP that, in theory, the potential benefits may not outweigh the potential harm but the question asked for evidence of a systematic assessment of expert opinion, which was not provided. The developer stated that the face validity presented in the validity section could be seen as evidence of a systematic assessment of expert opinion.
- The Standing Committee determined that it would not be appropriate to hold providers accountable for performance on this measure in the absence of direct empirical evidence of benefit to patients.

3403 Percentage of Prevalent Patients Waitlisted (PPPW)

Submission

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-0; M-3; L-5; I-10**

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.

Public and Member Comment

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- 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.
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assessment of expert opinion, which was not provided. The developer stated that the face validity presented in the validity section could be seen as evidence of a systematic assessment of expert opinion.

- The Standing Committee determined that it would not be appropriate to hold providers accountable for performance on this measure in the absence of direct empirical evidence of benefit to patients.