

KIDNEY CARE QUALITY ALLIANCE

TRANSPLANT WORKGROUP MEETING 1 SUMMARY AUGUST 20, 2021

Attendees: Sasha Couch; John Ducker MD (Co-Chair); Barry Friedman; Benjamin Hippen MD; Sumit Mohan MD, MPH; Krista Lentine MD, PhD; Rachel Patzer PhD, MPH (Co-Chair); Francesca Tentori MD, MCSI; Avram Traum MD; Kathy Lester JD, MPH; Lisa McGonigal MD, MPH

Not Present: Merida Bourjolly; Choli Hartono MD; Caprice Vanderkolk

MEETING SUMMARY

After welcoming remarks from the Co-Chairs and roll call, Dr. McGonigal reviewed the meeting agenda; provided an overview of the project scope and timeline and the Workgroup's charge and workplan; reviewed NQF endorsement criteria; and summarized existing facility-level transplant data limitations. The Workgroup then reviewed the Transplant Measures Environment Scan and Transplant Measure Concept Prototypes developed by KCQA staff. The meeting discussion is summarized below.

Meeting Deliverable:

- Identification of 1-3 dialysis facility-level Transplant Measure Concepts for the KCQA Steering Committee's consideration and approval.

Workgroup Charge:

- The Transplant Workgroup is asked to identify 1 (or 2-related) dialysis facility-level transplant performance measures; NQF endorsement will be sought for subsequent use in CMS's federal ESRD quality programs.
- The identified measure(s) must fall firmly within the realm of the dialysis facility's control.
- The identified measure(s) must meet NQF's *Feasibility* criterion, defined as follows:
 - Required data are readily available or could be captured without undue burden and can be implemented for performance measurement.
 - Required data elements are routinely generated and used during care delivery.
 - Required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic sources, a credible, near-term path to electronic collection is specified.
 - Data collection strategy (e.g., data source/availability, timing, frequency) can be implemented (e.g., already in operational use or testing demonstrates that it is ready to put into operational use).
- KCQA and the Workgroup must also be cognizant of potential unintended consequences when considering measures.

Data Limitations:

- Data specific to those steps in the transplant process that do fall within the dialysis facility's realm of control (education, referral, and [to a lesser degree] evaluation start) are not currently collected on a national level.
- Despite a longstanding push from stakeholders for CMS to collect referral data (in particular) in CROWNWeb, there has been no real progress on this to date. However, new CMS leadership is receptive to working more collaboratively with the renal community, and the KCQA Workgroup process could present a unique opportunity for progress in this regard. (Notably, KCQA has had success around similar issues in the past with another measure that was ultimately endorsed by NQF. Specifically, KCQA developed that measure [Medication Reconciliation], tested it with existing internal facility data, made the case for its importance at NQF, and then successfully lobbied CMS to incorporate the necessary data elements into CROWNWeb.)

- Consistent with NQF’s feasibility criterion, most facilities are already capturing referral data internally, and the case could be made for using a similar approach to the above. However, the validity and reliability of this data element, as currently collected, is unknown. The Workgroup noted there is a lack of uniformity across facilities regarding data granularity—e.g., not all facilities capture information on the healthcare professional who made the referral, which could be used to strengthen the data element through identification of a discrete accountable entity. Workgroup members suggested a provider TIN could be used to capture the referring provider; alternatively, the facility medical director could assume responsibility of ensuring referrals are occurring as appropriate. Workgroup members also noted the gold standard for tracking referrals in research has been transplant center referral receipt date, which may vary from the date on which the dialysis facility truly made the referral. Likewise, there is often a disparity between referrals and completed first evaluation, bringing into question the underlying validity of existing referral data (i.e., referrals could be made but not seen through to completion, meaning the data element is not a true reflection of the care that occurred).
- It was unclear how such discrepancies can be efficiently resolved; however, Members suggested a standardized definition of what constitutes a referral could be identified and recommended by the Workgroup, e.g., dialysis facility sends referral + 2728 + insurance information, etc. It was also noted that advancing technology can play a role in improving the state of transplant-related data, as well as care coordination and intercommunication between the facility and transplant center.

Environmental Scan:

The Environment Scan presented the 46 unique¹ transplant measures/measure concepts identified through staff’s review of public sources, grey and international literature, and a survey of KCQA member dialysis organizations for applicable measures being used internally for quality improvement. The majority of identified measures/concepts are variations on one of five overarching themes:

1. Referral rate or ratio measures.
2. Waitlisting or transplant rate or ratio measures.
3. Referral or waitlist outcome measures (e.g., *Percent of Referred Patients Waitlisted; Percent of Waitlisted Patients with Transplant; Time from Referral to Evaluation*).
4. Waitlist management measures (e.g., *Number Active and Inactive Patients on the Waitlist; Patient Notification within 10 Days of Listing or Delisting*).
5. Transplant education measures addressing both staff and patient education.

Transplant Measure Concepts:

Staff also drafted a list of 11 potential dialysis facility-level transplant measure concepts to be used as a starting point for the Workgroup’s deliberations. With each concept, potential strengths and limitations were noted, including identified barriers, data issues, and possible unintended consequences. The concepts and the Workgroup’s discussion around each are summarized below.

Transplant Referral Rate:

- *Description:* Percent of all dialysis patients in a facility referred for evaluation for transplant.
- *Strengths:*
 - Substantial room for improvement in this aspect of care.
 - Firmly within the dialysis facility’s realm of control.
 - Advancing and advocating for the measure would likely facilitate and expedite the creation and collection of national uniform referral data element.
- *Limitations:*
 - National referral data don’t currently exist.
 - Process measure; generally not as favored as outcome measures at NQF.

¹ Redundant metrics were eliminated; e.g., if a KCP organization is using a USRDS metric to track internal quality or if there were no discernable differences between two concepts from different sources, we did not list twice.

However, this particular process—dialysis facility referrals—has long been identified as a persistent barrier to increased transplant rates and may be viewed favorably.

- Unless structured properly, there is risk this could devolve into a “check-box” construct; inclusion of multiple “layers” of verifiable data and an accountable entity (e.g., date of referral, name or other unique identifier of the dialysis facility professional who made the referral) may negate this risk.
- *Discussion:*
 - Some Workgroup members expressed concern that a dialysis facility referral measure might spur “indiscriminate” referrals and overwhelm transplant centers. It was noted that referrals are only one of a series of barriers, and that all must be addressed to truly improve the transplant evaluation process.
 - Others appreciated this concern, but were less concerned about overwhelming transplant centers than ensuring dialysis facilities address those barriers within their control. It was noted that referral and waitlist rates remain shockingly low, and that transplant centers are far from being overwhelmed at this point in time. It was suggested that a carefully designed measure will help limit the tendency for indiscriminate or inappropriate referrals, and that this opportunity might present a unique opportunity to push for—and make progress on—national referral data collection. It was also noted that current guidance from HRSA and OPTN itself negates this concern: “Provider autonomy is important, as is the patient-provider relationship. However, the decision that a patient is not a transplant candidate should ideally be made by a transplant center, not preempted before evaluation. Early referral to transplantation should be encouraged as the default pathway for patients.”²
 - Others remarked that the socioeconomically disadvantaged are less likely to be referred, such that persistently low referral rates perpetuate transplant disparities. Referrals are a key aspect of valued kidney care and must be addressed to facilitate improved access, outcomes, and inequities.
 - Others agreed KCOA should not allow downstream issues in the evaluation process that are outside the control of the dialysis facility prohibit it from focusing on those processes that are in the facility’s control. It was suggested that the transplant center “bottleneck” is a separate issue that needs to be addressed via other policy levers beyond the scope of our charge. If we nevertheless let that bottleneck limit our scope, we are potentially squandering this unique opportunity to appropriately and definitively address persistent dialysis facility-level barriers (e.g., referrals) that are firmly within our realm of control.
- **Workgroup Decision: Retain for further consideration.**

Transplant Referral Opt-Out Rate:³

- *Description:* Percent of all dialysis patients assigned to a facility without a transplant center referral with a documented referral “opt-out” rationale.
- *Strengths:*
 - Substantial room for improvement.
 - Firmly within dialysis facility’s locus of control.
 - Would facilitate creation/collection of national referral data and more uniform

² OPTN, HRSA. [Educational Guidance on Patient Referral to Kidney Transplantation](#). September 2015. Accessed September 3, 2021.

³ Based on: Huml AM, Patzer RE, et al. An opt-out model for kidney transplant referral: The time has come. *Am J Transplant*. 2021;21:32-36.

transplant exclusion criteria.

- *Limitations:*
 - Currently no national referral (or “opt-out”) data collected.
 - Process measure (but, as above, identified as a persistent barrier to improvement).
 - Might be viewed as a “check-box” measure if not structured appropriately.
 - Would require risk adjustment or precisely defined exclusions to identify patients who are appropriate for opting out; however, absolute and relative contraindications to transplant very widely across states, regions, and even locally by transplant center, and comorbidity data are not readily available except through the CMS-2728, which is limited to incident comorbidities and of questionable reliability and validity.
 - Might still overload transplant centers.
- *Discussion:*
 - The same general referral issues were acknowledged, as above.
 - Workgroup members were not certain that an “opt-out” construct offers any advantages over the “opt-in” referral approach above and is more complicated.
 - It was noted that identifying comorbidities for exclusions or risk adjustment would be difficult; Form 2728 data are low quality and address incident patients only.
 - Patient preference/refusal would need to be captured, but data are not routinely captured and are of questionable validity; there is no mechanism to ensure refusal is a truly informed choice rather than a reflection of inadequate education or improper timing/wording of the query.
- **Workgroup Decision: Do not pursue.**

Standardized Transplantation Referral Ratio:⁴

- *Description:* Risk-adjusted ratio of observed-to-expected number of adult patients on dialysis referred for transplant evaluation.
- *Strengths:*
 - Firmly within dialysis facility’s locus of control.
 - Would facilitate creation/collection of national referral data.
 - Calculating expected numbers would offset tendency for indiscriminate referrals to meet measure criteria.
- *Limitations:*
 - Currently no national referral data.
 - Complex risk stratification; unclear what variables would be required and availability of such.
 - If comorbidities required, would need to limit to incident patients (CMS-2728).
- *Discussion:*
 - The same general referral issues as above were acknowledged.
 - The Workgroup agreed that establishing an expected value may effectively address concerns of indiscriminate referrals.
 - Given existing data limitations, however, it was unclear if this measure could be operationalized nationally, as a fairly complex risk adjustment is required to determine the “expected” value.
- **Workgroup Decision: Tentatively retain for further consideration.**

Rate of Referred Patients Who Were Waitlisted and/or Transplanted:

⁴ Sudeshna P, Plantinga LC, Patsan SO, Gander JC, Mohan S, Patzer RE. [Standardized transplantation referral ratio to assess performance of transplant referral among dialysis facilities.](#) CJASN. 2018;13(2):282-289.

- *Description:* Percent of all referred patients who were waitlisted and/or transplanted.
- *Strengths:*
 - Improved dialysis facility agency over simple waitlist metric (i.e., only those patients selected for referral by the facility would be included in the denominator and assessed for the waitlisting outcome; current waitlisting metrics include all patients in the denominator [with limited exclusions], regardless of whether the facility felt a patient was appropriate for referral or not).
 - Outcome measure (preferred by NQF).
- *Limitations:*
 - Currently no national referral data.
 - Underlying referral rate would be obscured as the primary focus of the metric is waitlisting.
 - Might reduce referrals by incentivizing “cherry-picking.”
 - Waitlisting/transplant still outside dialysis facility control.
- *Discussion:*
 - The same general referral issues were acknowledged, as above.
 - The Workgroup agreed the measure would increase facility focus on identifying and referring the most appropriate patients for transplant and would thus address the issue of indiscriminate referrals.
 - However, some agreed there may be significant and perverse pressure for facilities to “cherry-pick” referrals to perform well, such that the measure may *reduce* referrals overall. The Workgroup was thus not convinced the measure would ultimately improve care or outcomes.
- **Workgroup Decision: Do not pursue.**

Measure Set: Referral Rate + Rate of Referred Who Were Waitlisted and/or Transplanted:

- *Description:*
 - a. Percent of all dialysis patients referred to a transplant center for evaluation.
 - PLUS
 - b. Percent of all referred patients who were waitlisted and/or transplanted.
- *Strengths:*
 - Improved dialysis facility agency over straight waitlist metric.
 - Suggested as a paired set to drive referral rate and counterbalance perverse incentive to “cherry-pick” referrals.
 - Measure B is an outcome measure.
- *Limitations:*
 - Currently no national referral data.
 - Waitlisting/transplant still outside dialysis facility control.
- *Discussion:*
 - The same general referral issues were acknowledged, as above.
 - It was noted that this measure set combines the simple referral rate measure (1st concept) and the rate of those referred who were waitlisted measure (directly preceding concept). The advantage of this approach (over either individual measure) is that the two measures implemented together will serve to both increase facility focus on identifying and referring the most appropriate patients for transplant while concomitantly driving referral rates to counterbalance the perverse incentive to “cherry-pick” referrals.
- **Workgroup Decision: Retain for further consideration.**

Other Discussion Items:

Proposed Alternative Workgroup Scope and Charge

- One Workgroup member noted that if we want to ensure patients have optimal care, education, which is firmly within the dialysis facility's realm of control, is critical. It was suggested that a multistep iterative process measure addressing the education process would be the ideal performance measure and would have the greatest impact on care and outcomes. Such a measure could be constructed so that the education process is standardized, documented, verifiable, and tailored to the individual patients' clinical and social scenario (e.g., if it is confirmed that no living donor is available, that component of the education could be omitted). The Workgroup agreed with this premise and that development of such a measure would be the ideal. However, it was noted that the existing evidence base is not sufficient to identify a single education process that could be put forth as worthy of national adoption over other approaches. While it was suggested that a grass-roots effort could be undertaken to identify the appropriate process and piloted in a limited number of facilities, others in the Workgroup argued that such an endeavor is beyond the scope of the current project, which is focused on delivery of a discrete measure for near-term NQF endorsement consideration.
- Building upon the above, the Workgroup member proposed that near-term NQF endorsement of any of the previously referenced measures, in the absence of any existing supporting data sets, is unlikely; if the scope of the subcommittee is limited to identifying a measure likely to garner near-term NQF approval, he suggested the likely outcome is that the Workgroup would not be able to recommend *any* measure to the Steering committee for further consideration. If, however, the scope of the Workgroup was judged not to be limited by NQF-endorsable measures, the group might consider either endorsing a measure worthy of further consideration as a reporting metric to generate data that might serve as the basis for a future quality metric, and/or elucidate further the stepwise, iterative process measure outlined above.
- KCQA staff noted that the above proposed approach is a much broader scope than is currently approved by KCP/KCQA and would require significantly more time and resources than allotted. Second, KCQA specifically tasked the Workgroup with identifying a measure for NQF endorsement consideration in the near-term for use as an alternative to the CMS measures currently being deployed in the QIP and ETC model; the new proposal does not fit this bill and may be dismissed as being misaligned with the Workgroup's charge. Third, implementation of any product resulting from the education proposal would likely require opening the Conditions for Coverage for revision—an onerous task with varied and nuanced policy and financial implications that we suspect KCP/KCQA will be unwilling to tackle at this juncture. However, staff did acknowledge that the existing Conditions for Coverage are underdefined and do little to advance the patient education process. The Workgroup was asked to consider if it would be interested in expanding its scope to also define a series of detailed recommendations in this regard that could be submitted to CMS when it opens the Conditions for revision (timeline unknown).

Pediatric Patients

- The Workgroup agreed that while including pediatric patients in the measure(s) would benefit units that serve children and could conceivably disadvantage those that don't, it was noted that the percentage of pediatric patients is so small that it this decision will ultimately have little impact on facility performance or financial incentives. The Workgroup unanimously agreed that pediatric patients should be included in the KCQA measure(s).

Living Donor Focus

- The Workgroup suggested that a focus on increasing living donor evaluations should be a component of whatever measure KCQA develops.

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

The Transplant Workgroup will reconvene Friday August 27 (12-2 pm ET) to complete its review of the Transplant Measure Concept Prototypes and to identify its top 2-4 concepts for Steering Committee consideration/approval.