Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel Summary Report

September 24, 2021

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Practitioner Level Measurement of Effective Access to Kidney Transplantation Measure Development

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop practitioner level measures in the area of access to kidney transplantation for dialysis patients. The contract name is Kidney Disease Quality Measure Development, Maintenance, and Support. The contract number is 75FCMC18D0041, task order number 75FCMC18F0001. As part of its measure development process, the UM-KECC convenes groups of stakeholders who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

Introduction

This report summarizes the discussions and recommendations of the Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel (TEP) meetings convened on April 15, May 4, May 11, May 25, June 15, June 17, and June 22, 2021. All meetings were held virtually via Zoom video-conference. The TEP provided advice and expert input on the development of practitioner level measures in the areas of transplant waitlisting, referral, education, and other related aspects affecting access to kidney transplantation. The discussions were informed by an annotated bibliography of relevant literature compiled by UM-KECC and data provided by UM-KECC.

The TEP reviewed evidence and data, and held expert and stakeholder discussions, to determine the basis of support for the proposed measures. The key deliverables of the TEP included:

- Providing feedback and recommendations on draft measure specifications
- As needed, providing input on the necessary documentation forms to support submission of the measures to CMS for review, and to the National Quality Forum (NQF) for endorsement consideration
- As needed, TEP members may be asked to provide input to UM-KECC as they prepare responses to NQF and public comments

Technical Expert Panel Objectives

UM-KECC has been tasked by CMS to develop practitioner level quality measures that allow measurement of patient access to kidney transplantation. Topic areas may include waitlisting, referral, education, and other related aspects.

The results of numerous studies have indicated that the recipients of kidney transplants have better survival than comparable dialysis patients. The End-Stage Renal Disease (ESRD) Conditions for Coverage mandate a comprehensive reassessment of each patient annually, at minimum, with the revision of the Plan of Care. Both the patient assessment and Plan of Care should include reevaluation of treatment modality and transplant status. Specifically, Section 494.80(a)(10) of the revised Conditions for Coverage for ESRD Facilities, effective October 14, 2008, sets forth requirements for patient assessment with regard to transplantation referral: “Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for non-referral must be documented in the patient’s medical record.” Additionally, objectives CKD-12 and CKD-13 of Healthy People 2020 have the goal to “increase the proportion of dialysis patients wait-listed and/or receiving a deceased donor kidney transplant within 1 year of ESRD start (among patients under 70 years of age)” and “increase the proportion of patients with treated chronic kidney failure who receive a transplant". Substantial variations by facility and geographic region, as well as disparities by race and socio-economic status in transplantation rates raise concerns about current processes for provision of access to transplantation.

The 2021 TEP will build on the work of the 2015 TEP, which led to the development of two dialysis facility level metrics, the Standardized Waitlist Ratio and the Percentage of Prevalent Patients Waitlisted.

Technical Expert Panel Composition

A public call for nominations opened on January 15, 2021, and closed on February 15, 2021. Nominations were sought from individuals with the following areas of expertise or experiential perspectives:

- Transplant process expertise (from candidate evaluation through to transplantation) including transplant nephrologists, transplant surgeons, social workers, transplant coordinators/nursing
- Dialysis facility perspective on referral to transplant evaluation including nephrologists, nurses, social workers
- Transplant policy expertise
- Individuals with consumer/patient/family perspective and consumer and patient advocates; specifically, patients with experience with transplant work-up, time on the waitlist, transplantation and failed transplants
- Individuals with research expertise with Medicare data and issues pertaining to access to kidney transplantation;
- Individuals with perspectives on healthcare disparities in access to transplantation
- Expertise in performance measurement and quality improvement

The following individuals were selected to serve on the TEP. Dr. Rachel Patzer and Mr. Bobby Howard served as TEP co-chairs. The TEP was facilitated by Dr. Vahakn Shahinian from UM-KECC.

Name, Credentials, Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
David Axelrod, MD, MBA, Transplant Surgeon	University of Iowa Iowa City, IA	Consulting arrangements with CareDx and Talaris; active research into outcomes after kidney and liver transplant using linked datasets.
Amy Waterman, PhD, Professor of Medicine, Nephrology	UCLA Nephrology Los Angeles, CA	None
Bobby Howard, Patient, Director, Multicultural Donation Education Program	LifeLink of Georgia Association of Organ Procurement Norcross, GA	None
Jesse Schold, Mstat, PhD, Research Director	Cleveland Clinic Chagrin Falls, OH	None
Emily Watson, MSW, LCSW, Social Worker	Satellite Healthcare, LLC San Jose, CA	None
Krista Lentine, MD, PhD, Professor of Medicine	American Society of Nephrology Policy & Advocacy Committee Saint Louis University ASN Alliance for Kidney Health St. Louis, MO	CareDx, consulting. Sanofi, speakers' bureau.
Bryan N. Becker, MD, MMM, Physician	DaVita, Inc. Hinsdale, IL	Employed by DaVita, Inc., and owns DaVita, Inc. stock.

Name, Credentials, Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
John T. Ducker, MD, Transplant Nephrologist	Nephrology Associates of Northern Illinois and Indiana Renal Physicians Association Ft. Wayne, IN	None
Teri Browne, PhD, MSW, Associate Dean and Professor	University of South Carolina College of Social Work Irmo, SC	None
Rachel Patzer, PhD, MPH, Director, Health Services Research Center	Emory University School of Medicine Atlanta, GA	None
Della Major, MA, Patient	National Forum of ESRD Networks, member of the Kidney Patient Advisory Council Chicago, IL	None
Sumit Mohan, MD, MPH, Physician and Epidemiologist	Columbia University American Society of Nephrology Alliance for Kidney Health Irvington, NY	None
Dawn P. Edwards, Patient	National Forum of ESRD Networks Kidney Patient Advisory Council Jamaica, NY	None
Geraldine Zingraf, DNP, MBA, RN, CNN, CCTC, Transplant Administrator	Edward Hines, Jr. VA Hospital Franklin Park, IL	None
Sasha Couch, Patient	Renal Support Network Los Angeles, CA	None
Contractor Staff		
Vahakn Shahinian, MD, Professor	Nephrology, Internal Medicine University of Michigan, Kidney Epidemiology and Cost Center	None
Abhijit Naik, MD, Assistant Professor	Nephrology, Internal Medicine University of Michigan, Kidney Epidemiology and Cost Center	None
Jonathan Segal, MD, KECC Director, Professor	Nephrology, Internal Medicine University of Michigan, Kidney Epidemiology and Cost Center	None
Zhi (Kevin) He, PhD, Associate Research Professor	Biostatistics, School of Public Health University of Michigan, Kidney Epidemiology and Cost Center	None
Jian Kang, PhD, Associate Professor	Biostatistics, School of Public Health University of Michigan, Kidney Epidemiology and Cost Center	None
Ananda Sen, PhD, Research Professor	Department of Biostatistics University of Michigan, Kidney Epidemiology and Cost Center	None
Valarie Ashby, MA, Managing Director & Director of Analytic Support	University of Michigan, Kidney Epidemiology and Cost Center	None
Mia Wang, MS, Senior Analyst	University of Michigan, Kidney Epidemiology and Cost Center	None

Name, Credentials, Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
Dan Shaffer, MS, Senior Analyst	University of Michigan, Kidney Epidemiology and Cost Center	None
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Tammie Nahra, PhD, Lead Analyst	University of Michigan, Kidney Epidemiology and Cost Center	None
Katrina Price, MPH, Intermediate Analyst	University of Michigan, Kidney Epidemiology and Cost Center	None
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Xizhao (Jenny) Li, MS, Lead Programmer	University of Michigan, Kidney Epidemiology and Cost Center	None
Jennifer Sardone, BA, PMP, Senior Project Manager	University of Michigan, Kidney Epidemiology and Cost Center	None
Wen Wang, PhD Student	Biostatistics, School of Public Health University of Michigan, Kidney Epidemiology and Cost Center	None
Nicholas Hartman, PhD Student	Biostatistics, School of Public Health University of Michigan, Kidney Epidemiology and Cost Center	None
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Summary of TEP Deliberations

Preliminary Activities

Information Gathering - Environmental Scan and Literature Review

Prior to the in-person TEP meeting, UM-KECC provided TEP members with an annotated bibliography of published literature (Appendix B) related to access to transplantation. UM-KECC conducted a literature search in February, 2021 limited to articles published in the English language since January 6th, 2015 (the end date for the literature search performed for the prior Access to Transplantation TEP). A guideline summary and environmental scan of related quality measures was also provided.

TEP Charter

The TEP Charter (Appendix A) was distributed to the TEP members for review prior to the first meeting and was approved by the TEP members. At the first TEP meeting, key elements of the charter were highlighted, including the priority of developing practitioner level quality measures related to access to transplantation.

Key elements highlighted included expectations of TEP members to use existing data and their expert opinion to formulate recommendations to UM-KECC regarding the development of a draft measure that addresses potentially important quality gaps in access to transplantation. Recommended measures should be evidence based, scientifically acceptable (reliable and valid), feasible, and usable by CMS, providers, and the public.

Background

Summary of current state of access to kidney transplantation

The TEP co-chairs gave a summary on the topic of access to kidney transplantation, including benefits of kidney transplantation, and the steps to kidney transplantation. Mr. Howard began with a general overview, stating that there are no clinical trials directly comparing transplantation to dialysis; however, there are multiple studies using observational comparisons between transplanted patients and waitlisted controls to demonstrate that life expectancy is substantially greater with transplantation. Similarly, quality of life, overall, favors transplantation for both adjusted and unadjusted mean differences in the 36-Item Short Form Health Survey questionnaire (SF-36) scores.

The co-chairs also provided an overview on data relating to steps in the process towards kidney transplantation.

- Steps of referral, evaluation start, and evaluation completion are not measured in national surveillance data, although they are vital components of the process.
    - Dr. Patzer described her Southeastern consortium collection of referral data; the initiation of this effort started as voluntary through the ESRD network as the data coordinating center and eventually expanded to an NIH-funded consortium. Relevant data collection included the date transplant centers received the referral from the dialysis facility.
    - Based on that regional data, factors associated with non-referral included White race, older age, and more comorbidities; of patients referred, only 21% were waitlisted or received a transplant within one year of referral; Black race was associated with a lower likelihood of waitlisting within a year of referral.

- Transplant waitlisting, and active versus inactive status on waitlist, as well as transplant events, are well recorded in national surveillance data.
    - Data from literature published by some of the TEP members were presented to show no meaningful improvement in waitlisting rates over the last 2 decades. There are demonstrated associations with income and socioeconomic status (SES), where patients with lower SES have less access to the waitlist. Moreover, there are persistent racial and ethnic disparities in waitlisting over time as well as active vs inactive status on the waitlist. A study showing racial disparities in receipt of living donor kidney transplants was also cited.

- Data on receipt of information on the option for kidney transplantation is not reliable
    - Mr. Howard discussed a study showing that as many as 30% of patients are not informed of the kidney transplant option on the CMS-2728 form (the End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration form) collected by CMS. Another study demonstrated poor concordance between such reporting on the CMS-2728 form and patient self-report of receipt of information about kidney transplantation.

    - Selected other studies were presented pertaining to education on kidney transplantation. In one, a majority of nephrologists stated that at least 20 minutes of time should be spent educating patients on the kidney transplant option, but most did not report spending that much time. Another study demonstrated that dialysis facilities with educators using more than three educational strategies are more strongly associated with higher levels of waitlisting among their patients.
    - Mr. Howard described that his experience as a patient and the work he witnesses in the community in terms of educational strategies mirrors findings in the studies.

Summary of previous measure development activities pertaining to access to kidney transplantation

Dr. Shahinian described the results of previous clinical TEPs held by CMS on access to kidney transplantation. In April 2015, UM-KECC held a TEP for development of dialysis facility measures related to access to transplantation. The TEP deliberations included discussion relating to a measure assessing provision of education about kidney transplantation. Although deemed to be of great importance, given the absence of valid national data capturing provision of such education and the unavailability of validated tools to assess high quality education, no specific measures were recommended for development. There was also broad support for and discussion surrounding a measure structured around referral for transplant evaluation but the absence of a national data collection mechanism limited the ability to conduct further development work. Ultimately, the TEP formulated and moved forward with development of two measures relating to transplant waitlisting. The standardized first kidney transplant waitlist ratio (SWR) focused on the first year after initiation of dialysis to encourage early waitlisting, whereas the percentage of prevalent patients waitlisted (PPPW) focused on longer term, ongoing maintenance of patients on the waitlist.

Both measures were submitted to the National Quality Forum (NQF) but were not endorsed, due primarily to a failure to meet the evidence requirement; the body of evidence provided in support of the waitlist measures centered around the benefits of transplantation, not specifically the benefit of waitlisting per se. Furthermore, the NQF Renal Standing Committee felt the measures insufficiently addressed exclusions, risk adjustments, and patient preference (i.e. a patient who does not want to be evaluated for transplant or waitlisted). Although these measures were not endorsed by the NQF, they were included in public reporting programs such as Dialysis Facility Compare (DFC) as well as the End Stage Renal Disease Quality Incentive Program (ESRD QIP).

Comments from the TEP were invited relating to this prior work. One TEP member expressed surprise at the difficulty in passing the evidence standard for NQF endorsement, given that waitlisting is a key and necessary step towards receipt of a kidney transplant. The TEP member thought empirical evidence of the benefits of waitlisting could easily be generated. Additionally, the member expressed the sentiment that a measure focusing on the prevalent dialysis population may be more preferable than one only focusing on the first year after initiation of dialysis, such as the SWR, given the ongoing importance of waitlisting beyond the first year.

Another TEP member raised concerns about reliability of the measures, and inquired about stability of dialysis facility performance over time. In addition, they noted that issues of reliability may be more challenging with practitioner level measures given sample sizes of patients may be smaller than for dialysis facilities.

Discussion of potential areas of focus for practitioner level measures

Dr. Shahinian reminded the TEP members of the measure evaluation criteria and set the goal for initial discussion around the area of focus for the measures while keeping in mind issues of importance, validity, reliability, and usability.

TEP members shared their thoughts on a number of high-level issues that could inform measure development, including:

Target of the measures. Per the charter, the focus of the TEP was to consider measures at the practitioner level, keeping in mind issues of feasibility of attribution and appropriateness of directing measures to practitioners. Following a question from the TEP, it was clarified that the term practitioner in this instance referred to nephrologists, along with advanced practice providers under nephrologist supervision. Dr. Shahinian further explained potential uses for the measures that this TEP may develop, such as the Quality Payment Program (created through MACRA, the Medicare Access and CHIP Reauthorization Act of 2015). After introducing the compensation methodology, he went on to describe the Merit-based Incentive Payment System (MIPS) and how quality measures contribute a portion of the MIPS score. TEP members noted the importance of other providers, such as dialysis facilities and transplant centers, in improving access to kidney transplantation and that alignment of incentives across all the groups could create additional momentum to improve practice. One TEP member also brought up other models of care focused on improving access to transplantation, such as the ESRD Treatment Choices models.

Issues of data availability. There is currently a lack of national data for several of the steps to transplantation, most importantly education and referral. The current checkbox on CMS-2728 form acknowledging receipt of information about the transplantation option was deemed insufficient for use in a measure. Although education was viewed as a crucial step towards transplantation, no national data or tools to capture provision of high quality education are currently available for incorporation in a measure. Ongoing regional work on gathering data on referral demonstrates the potential feasibility of eventually establishing a national platform for such data collection which could eventually be incorporated into related measures.

Appropriateness of waitlisting measures at the dialysis practitioner level. Although national data on waitlisting is readily available, there was substantial discussion around whether waitlisting was under the control of dialysis practitioners. In particular, concerns were raised that waitlisting is highly influenced by environmental factors, including, but not limited to transplant center practices, organ supply, and geography within the region of the dialysis facility; therefore, any measure directed at dialysis practitioners should include adjustments for such factors beyond practitioners’ control.

Pre-ESRD care. Several TEP members emphasized the critical importance of care directed at access to kidney transplantation prior to ESRD, with a view to achieving pre-emptive transplantation whenever possible. This sentiment was noted, but it was ultimately clarified that the mandate of the current TEP was to focus on the ESRD population.

Social determinants of health and socioeconomic factors. Several TEP members expressed concerns about how these serve as a significant barrier to transplant referral and waitlisting. One TEP member who is a patient advocate provided the experience of patients not being referred due to preconceived notions about the patient's ability to pay for or ability to sustain a transplant. Substantial further discussions on this point were held, and are documented in subsequent sections.

These topics are explored further in the following sections, which focus on three areas of potential measure development: transplant waitlisting, transplant referral, and transplant education.

Transplant Waitlisting

Data Presentation

Dr. Shahinian presented the TEP with a series of analyses at the facility and practitioner levels to help inform the waitlist discussion (Appendix E).

Rationale for a practitioner level transplant waitlisting measure

Dr. Shahinian proposed the following rationale for discussion by the TEP. Although the ultimate decision to waitlist a patient belongs to the transplant center, the dialysis practitioner can assist with ensuring the patient receives high quality education about transplantation, is referred for evaluation, maintained in good health status while on dialysis, and completes any necessary testing for the transplant evaluation, all of which contributes to patients ultimately being approved for waitlisting and being maintained on the waitlist. Factors outside practitioner control that influence waitlisting, either in terms of patient characteristics, or transplant center behavior, could in part be accounted for through appropriate adjustments and exclusions in order for measures to be a valid reflection of practitioner quality.

Subsequent discussions relating to the rationale for practitioner level waitlisting measures reflected some agreement with the idea that practitioners contribute importantly to steps toward waitlisting. However, there were ongoing concerns expressed about the ultimate control exerted by transplant centers in the decision to waitlist. In particular, a number of TEP members called attention to wide variations in transplant center practices with respect to waitlisting criteria, exclusion criteria, and the likelihood of waitlisting. Another point raised was that there are patients in geographic locations with ready access to more than one transplant center, which increases the likelihood of finding a center where they would be waitlisted. Geographic proximity to multiple transplant centers is not necessarily equitable or feasible across the country; that variable could impact the practitioner simply by virtue of where they are located or the SES of the patients for whom they are providing care. Another TEP member cautioned against using waitlisting at the practitioner level given competing incentives on the transplant center side. For example, transplant centers are measured on their transplant rate off the waitlist, and may deliberately limit which patients they waitlist to optimize their transplant rate outcome.

Preliminary discussions about measure structure

Individual practitioner vs group practice

One topic that was addressed early on was whether the measures would be directed at individual practitioners versus group practices. The choice was made to focus on group practice measures for two reasons. First, group practice measures are more likely to be statistically reliable given larger sample sizes of attributed patients. Second, group practice measures can avoid issues of care attribution that can occur in the dialysis setting where patients are frequently seen by several different practitioners within a practice.

Data analytic issues and the population of patients included in the measures

Dr. Shahinian described the consequences of adapting existing dialysis facility level waitlisting measures to the practitioner level. In order to attribute patients to a practitioner, the Medicare claim for the monthly capitated payment for dialysis is used to find the national provider identifier (NPI) for the individual physician or the tax identification number (TIN) for the group practice. Although a TIN could be attributed to a single physician practicing alone, the TIN frequently represents physicians working in groups. Because the attribution methodology is based on Medicare claims, such measures would necessarily be limited to the population of patients with Medicare Fee-For-Service (FFS) insurance. In contrast, patients can be attributed to facilities without relying strictly on Medicare claims, because data on patient placement is found in CROWNWeb and waitlist data is found in Organ Procurement and Transplantation Network (OPTN) data. Thus, the current structure of the dialysis facility PPPW measure is inclusive of all prevalent dialysis patients, regardless of insurance, whereas a measure at the practitioner level would be limited to Medicare FFS patients only. In focusing on Medicare only patients, the population is reduced from 460,000 unique patients to about 280,000, with the excluded patients having other forms of insurance such as Medicare Advantage, Medicaid or commercial insurance. The overall Medicare FFS waitlist rates are slightly higher than the overall waitlist rate; however, the facility PPPW for Medicare FFS patients and the facility PPPW for all patients are highly correlated, suggesting that a focus on Medicare FFS patients only may not substantially distort the assessment of quality or waitlisting performance for facilities, at least. At the group practice level, a similar comparison cannot be made as the analysis can only be performed among Medicare FFS patients, but wide variability in performance across facilities was noted in analyses performed by UM-KECC and presented to the TEP.

The current dialysis facility SWR measure was intended to specifically incentivize rapid waitlisting upon initiation of dialysis and is focused on the first year following dialysis initiation. Whereas 60% of the prevalent population on dialysis has Medicare FFS insurance, a minority of patients initiate dialysis with Medicare FFS insurance; focusing only on Medicare FFS patients only would therefore be much more problematic for the SWR measure. For a potential practitioner level SWR measure, attribution of patients to practitioners without restriction to only Medicare FFS patients could be achieved using the CMS-2728 form, which identifies the attending physician. Preliminary analyses performed by UM-KECC demonstrate that there is about a 75-80% concordance rate between group practices identified through CMS-2728 form (based on the group practice of the attending physician) and those from Medicare FFS claims, among the set of patients with available data.

Beyond issues of practitioner attribution, restricting measures to patients with Medicare FFS insurance also allows for robust adjustment or exclusion of a wide range of comorbidities identified through codes on the Medicare claims. Although comorbidity information is also present on the CMS-2728 form, it is limited to a smaller set, and may not be as valid for patients who are not relatively proximate to the initiation of dialysis, when the form is completed.

While acknowledging the need and benefits of restricting the measures to the Medicare FFS population, a number of TEP members were nevertheless seriously concerned about the implications of the failure to include patients with other forms of insurance. The population of patients with Medicare Advantage (MA) was a particular concern, given rapid growth expected within the ESRD population over the coming years with the recent changes in policy. One TEP member noted that people who enter into MA plans may have significantly different characteristics, and quality measures focusing only on Medicare FFS patients would be taken as reflecting a provider’s entire practice, even though only based on a subset of patients. Another TEP member agreed, although noting this may be more of an issue several years from now as the MA population grows.

The UM-KECC team presented the case, and several TEP members voiced agreement, to continue with development of measures directed at Medicare FFS patients. This was based on the fact that the Medicare FFS dialysis population will likely remain sizeable even over the next several years of expected growth within the MA dialysis population, and the performance gaps and disparities that are known to exist support the need for measures within this group of patients. Furthermore, on theoretical grounds practitioner performance within the panel of Medicare FFS patients is likely to be reflective, at least in part, of practitioner quality overall. The general economics literature shows that physicians tend to treat patients within their practice similarly, irrespective of individual patients’ insurance coverage. More recent data examining bundled care programs targeting Medicare FFS patients have shown spillover benefits to MA beneficiaries. Finally, adjustment for social risk that could be incorporated into the measures may also mitigate concerns about systematic differences in characteristics of the MA versus Medicare FFS populations.

Dr. Jesse Roach from CMS joined the TEP to comment on their position on this issue. Although the MA population is increasing, a fair number of CMS beneficiaries are still Medicare FFS and a measure of the quality of care that they are receiving from practitioners is important and something that CMS would like to have in their programs. In addition, he noted that measures are continually monitored and reassessed, and can be revised if data suggests that changes are needed. He reiterates that even if limited to the

Medicare FFS population, the measures can still be beneficial given demonstrable performance gaps and disparities in that group. Finally, he acknowledged that improving availability of data on MA patients is a high priority.

Incident vs prevalent measures

Dr. Shahinian reviewed the differences in rationale for the PPPW versus the SWR measures. By examining patients currently waitlisted within the prevalent dialysis population, the PPPW tracks the longer term goal of maintenance of patients on the waitlist. In contrast, the SWR targets an incident population of patients initiating dialysis and uses a time-to-event analytic framework in order to construct a measure that incentivizes getting people waitlisted as soon as possible within a year of starting dialysis.

A TEP member voiced support for use of a time-to-event analytic framework to capture new waitlisting events. However, they were concerned with limiting such a measure only to the first year after dialysis initiation, as the current facility SWR measure does, given a substantial portion of new waitlisting events occur for patients beyond their first year after dialysis initiation. Dr. Patzer also noted that, according to the United States Renal Data System Annual Data Report, only about 13% of incident ESRD patients are waitlisted or receive a transplant within the first year, including pre-emptive transplants or waitlisting; therefore, examining patient outcomes beyond the first year is important. A TEP member raised a concern with use of a prevalent measure to assess the quality of practitioner performance relating to waitlisting. If a practitioner refers to transplant centers that efficiently transplant patients (a desirable outcome), thereby rapidly removing them from the waitlist, they may appear to perform poorly on the prevalent waitlisting measure. Dr. Shahinian commented that this concern had been previously raised with respect to the facility PPPW measure. This was addressed by the UM-KECC team through analyses which adjusted the facility PPPW for regional variation in transplantation rates, finding the variation did not meaningfully impact facility performance on the measure.

Active Status on the Waitlist

The current facility PPPW measure only assesses whether patients are waitlisted, without regard for active vs inactive status. The TEP discussed whether a waitlisting measure that focused on active waitlisting would be valuable. Following implementation of the new Kidney Allocation System, time on the waitlist is dated to the start of dialysis for all patients, regardless of when the patient is ultimately waitlisted. This change arguably makes the timing of waitlisting less urgent (which formerly may have been done even when the patient wasn't immediately ready for transplantation, simply to allow accrual of wait time) and therefore active waitlisting, the more relevant outcome. In response to a question about the impact on measure reliability of focusing only on active waitlisting, Dr. Shahinian noted that a substantial portion of overall waitlisted patients are in active status, and therefore there are unlikely to be concerns in that regard.

Despite the theoretical arguments in favor, a number of TEP members raised various concerns about developing a measure solely focused on active waitlisting. First, any waitlisting event, whether in active or inactive status reflects substantial efforts of dialysis practitioners, patients and transplant centers, and may also provide emotional benefits and hope to patients on dialysis. Second, there was a concern that communication from transplant centers to dialysis practitioners about waitlisting status, along with the reasons for patients being placed into inactive status, is not done consistently. Therefore, without active collaboration between practitioners and transplant centers it may be difficult for practitioners to effectively influence whether their patients are actively waitlisted. Third, there is substantial variability across transplant centers in their practices and criteria with respect to activity on the waitlist, and dialysis practitioners may not have much control over that.

Discussion of prototype measures

Dr. Shahinian provided the following measures as prototypes for discussion:

- First Year Standardized Waitlist Ratio for the first year aggregated across 3 years
- Prevalent Standardized Waitlist Ratio that accounts for patient transfers and includes adjustment for dialysis vintage
- Percentage of Prevalent Patients Waitlisted (PPPW)
- Active Percentage of Prevalent Patients Waitlisted (aPPPW)

Measure	Numerator	Denominator	Practitioner Assignment	Population
First Year Standardized Waitlist Ratio	New waitlist or living donor kidney transplant events (in those not already on waitlist) within the first year of dialysis initiation	Expected number of events based on the risk adjustment model (time to event model)	Group practice level, aggregating from individual practitioner on CMS-2728 form to group practice tax identification number	Potentially can include all patients on dialysis, if practitioner assignment and comorbidity adjustment is done using CMS-2728 form
Prevalent Standardized Waitlist Ratio	New waitlist or living donor kidney transplant events (among those not already on waitlist), includes patients at any time beyond initiation of dialysis	Expected number of events based on risk adjustment model (time to event model)	Group practice level, aggregating from individual practitioner on Medicare dialysis claims to group practice tax identification number	Limited to Medicare Fee-for-Service patients for practitioner assignment beyond first year of dialysis initiation and comorbidity adjustment from Medicare claims
Percentage of Prevalent Patients Waitlisted	Number of patient months in which patients at the dialysis facility are on the waitlist as of the last day of each month during the reporting year.	All patient-months for patients who are under the age of 75 as of the last day of each month during the reporting year	Group practice level, aggregating from individual practitioner on Medicare dialysis claims to group practice tax identification number	Limited to Medicare Fee-for-Service patients for practitioner assignment beyond first year of dialysis initiation and comorbidity adjustment from Medicare claims
Percentage of Prevalent Patients	Number of patient-months in which patients at the dialysis facility are on the waitlist	All patient-months for patients who are under the age of 75 as of the last	Group practice level, aggregating from individual practitioner on Medicare dialysis	Limited to Medicare Fee-for-Service patients for practitioner assignment beyond

Measure	Numerator	Denominator	Practitioner Assignment	Population
Waitlisted in Active Status	in active status as of the last day of each month during the reporting year	day of each month during the reporting year	claims to group practice tax identification number	first year of dialysis initiation and comorbidity adjustment from Medicare claims

The TEP discussed several categories of adjustments and exclusions for these proposed measures, described below.

Social Risk Adjustment

Dr. Shahinian provided the TEP with an overview of social risk factors, which are conditions that may influence health outcomes as much as or more than medical care, including SES, race, ethnicity, cultural context, gender, social relationships, residential and community context, as well as health literacy. In order to be accounted for in a quality measure, these factors must possess a conceptual and empirical relationship to the healthcare output, preceding care delivery, and not be a consequence of the quality of care or something the provider can manipulate. If the provider can control the potential risk factor, then it should not be adjusted for. Broadly speaking, a rationale in favor of adjustment for social risk is that it may potentially help avoid penalizing providers who disproportionately care for populations with increased risk. On the other hand, adjustment may actually serve to sustain the existing disparities by effectively “giving a pass” to differences in outcomes by social risk categories, rather than incentivizing practitioners to work to overcome the existing barriers. Therefore, the decision to include adjustment for social risk requires careful consideration. Another challenge with social risk adjustment is the limited availability of data that adequately captures it. Available variables potentially include race, ethnicity, sex, insurance or dual Medicare-Medicaid eligibility, as well as place of residence (e.g. based on zip code or census tract).

The TEP members were invited to discuss the issue of social risk adjustment. There was broad agreement that a strong conceptual/theoretical basis for adjustment in this context exists, given the well-known impact of social determinants on the outcome of waitlisting, and the plausible variation across practitioners in the social risk of populations under their care. A TEP member provided a specific example, such as the inability of a patient to afford costly but important medications beyond immunosuppressive therapies (e.g., anti-viral medications) after the transplant, which could lead to a transplant center choosing to not approve them for waitlisting. Patient members of the TEP were especially encouraged to voice their thoughts, and several provided anecdotes supporting the importance of social risk, including issues of resources, transportation and ability to afford medications. One TEP member did reflect that dialysis practitioners had a responsibility and could help their patients with some of these issues. Dr. Patzer made the point that how these measures are implemented matters with respect to whether there should be risk adjustment. For example, it may be valuable for practitioners to receive information on their unadjusted performance in patients within categories of social risk in order to develop mitigating strategies. However, within pay for performance programs, if no social risk adjustment is done, practitioners with large proportions of patients with high social risk may end up penalized, leaving less resources for them to help those patients.

Ultimately there was agreement that some social risk adjustment is indicated for waitlisting measures, though it was acknowledged that data availability was limited. Potential variables for adjustment considered included dual Medicare-Medicaid eligibility, and those based on place of residence, such as the Area Deprivation Index (ADI). The group briefly discussed the issue of using race or ethnicity as a proxy for social risk and its appropriateness. Dr. Jesse Roach from CMS noted that from their perspective, they tend to deem adjustment based just on race as inappropriate and would prefer some of the other social determinants of health in the measure.

Medical exclusions or adjustments

Dr. Shahinian reviewed current exclusions for the dialysis facility waitlist measures, including: patients age 75 years or older, nursing home residence, and residence in a hospice. There was broad agreement from the TEP on these exclusions for the practitioner waitlist measures.

Dr. Shahinian then presented the TEP for their consideration the comorbidity adjustment strategy that has been used for several other NQF endorsed dialysis facility quality measures. There are two main sources of comorbidity data: first, the CMS-2728 form, which provides a limited set of comorbidities present at initiation of dialysis, and is most relevant proximate to ESRD; second, Medicare claims, which are limited primarily to the Medicare FFS population, and utilizes International Classification of Diseases (ICD) codes for diagnoses. For the latter a strategy for choosing a set of diagnosis codes is necessary as it is impractical to adjust for thousands of codes in a model for the quality measures. Although CROWNWeb contains some information, such as vascular access data and selected labs, it is likely to be too limited for robust comorbidity adjustment. An option for collating ICD diagnosis codes is the Clinical Classification System (CCS) developed by the AHRQ which includes 282 groupings or collections of ICD codes; examples of these groupings include cancer of the lung, opioid dependence, dementia, and below-knee amputation status. The rationale for comorbidity adjustment in the context of waitlisting measures is to account for reasons patients may appropriately not be waitlisted for medical reasons. A proposed plan would be to use a statistical selection process to focus on the CCS groupings most predictive of short-term mortality, and therefore most likely to preclude waitlisting.

Dr. Shahinian showed a table that demonstrated the group practice SWR measure adjusted vs unadjusted for comorbidities based on the CMS-2728 form. The values were highly correlated, with only rare reclassification of group practice performance based on comorbidity adjustment. Dr. Shahinian pointed this out not to justify necessarily not having comorbidity adjustment, but rather to allay some concerns over whether inclusion or not of particular co-morbidities in the model will make a meaningful difference.

Overall, TEP members felt that robust comorbidity adjustment was important for a waitlisting measure, given variability of transplant center waitlisting acceptance criteria. Several TEP members offered up specific examples of comorbidity that may be important as exclusions. One TEP member brought up the current ESRD Treatment Choices (ETC) model, which has dementia as an exclusion, and felt it would be important for harmonization to use that for any waitlist measures developed as a product of this TEP. Other conditions suggested included active cancers, homelessness, high body mass index (>45 kg/m^2), oxygen dependence and uncontrolled substance abuse disorders. Dr. Shahinian responded that not all of these may be appropriate, either because of difficulty defining them adequately through ICD codes alone, their relative rarity in the dialysis population or because there may not substantial variability in them across practitioner groups, to include them in the quality measures. However, he noted that these could be examined in further development work conducted by the UM-KECC team on the waitlist measures.

Patient Preference Exclusion

Given the issue of patient preference was raised by the NQF Renal Standing Committee when the dialysis facility waitlist measures were discussed, Dr. Shahinian invited the TEP to weigh in on whether a patient preference exclusion (i.e. if a patient does not want a transplant) would be appropriate. Although the TEP broadly acknowledged the benefits of transplantation for most patients, and that proper ongoing education about these benefits is important, at least one member felt there were scenarios in which patients may reasonably not want to be waitlisted. The example given was the older patient (e.g. 70-75 years of age) in a region with long wait times, who may feel they are highly unlikely to ever receive a transplant, and therefore wish to forgo the evaluation process. Another TEP member made the point that adjustment for median wait time in the region may help mitigate such a concern, but also raised the question of the frequency and extent to which patient desire not to be transplanted would systematically differ across practitioners – if relatively rare and randomly distributed it would not necessarily need to be incorporated into the measure. Other TEP members also raised concerns that it may be hard to appropriately capture patient preference, as it can be highly influenced by how information is provided to patients by practitioners. A simple checkbox is therefore unlikely to be valid. Overall there was broad agreement by the TEP that no exclusion for patient preference should be included in the waitlist measures.

Transplant Center Adjustment

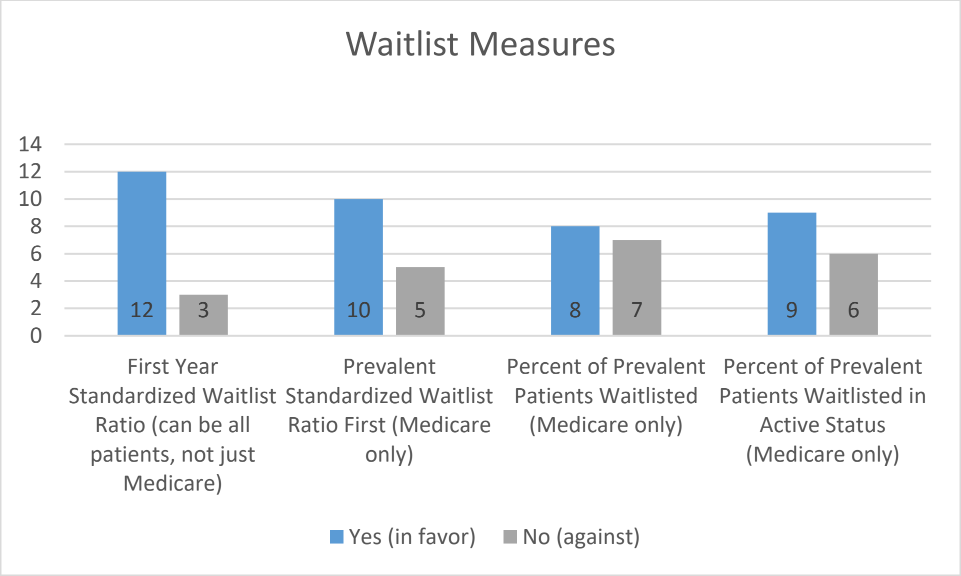
Dr. Shahinian presented the idea of a transplant center adjustment that could in theory account for some of the transplant center side factors affecting waitlisting beyond dialysis practitioner control. In order to adjust for the transplant center in the models, each patient would need to be assigned to a transplant center, regardless of their own waitlisting status. This could be achieved by examining historically where patients living in a particular zip code were waitlisted. By adjusting for the transplant center itself (e.g. including transplant center as a random effect in the models), it may be possible to broadly capture the effect of transplant center behavior, without necessarily adjusting for specific characteristics of the transplant center. The alternative, though not necessarily mutually exclusive approach, would be to adjust for specific transplant center characteristics that are deemed important. One example would be transplant rates within the transplant center. Dr. Shahinian further noted there is a precedent for a similar type of adjustment approach with one of the dialysis facility measures, the standardized readmission ratio. In this measure, there is an adjustment for a hospital effect and its impact on readmission, so the measure is capturing elements that are outside of dialysis facility control that can affect readmission at the hospital.

A TEP member asked Dr. Patzer to elaborate on an approach that she mentioned, which would assign dialysis patients to the appropriate catchment area of a transplant center, since there are 260 transplant centers across the country, with some zip codes including multiple transplant centers versus others that are more spread out within a particular service area. Dr. Patzer noted that preliminary work on this has been published recently that assigned patients to centers based on historical waitlisting patterns within hospital referral regions; however, there may be overlaps with multiple transplant centers in the same region, so the details would need to be sorted out in development work for the best method to assign a transplant center adjustment for patients. Another TEP member noted that some factors (such as organ supply) may be similar for transplant centers within the same geographic area, so the issue of particular transplant center assignment may not necessarily be problematic. Although a transplant center adjustment may not capture all nuances of transplant center behavior, there was broad agreement by the TEP that it would be desirable to include in the measure to mitigate the variability in transplant center practices that dialysis practitioners may face. The UM-KECC team committed to performing development work to include such an adjustment in the waitlisting measures.

Voting results and final comments

UM-KECC sought feedback from the TEP at the conclusion of the virtual meetings through a vote on each of the proposed, provisional measures based on discussions held to date by the TEP, recognizing that additional development work would need to be performed by the UM-KECC team. The input served as the foundation for the subsequent, ongoing development work and strategy for measure specifications for the waitlist measures. Individual TEP members were asked, “Please indicate whether you support continued development of the following waitlist measures” with the options of “yes (in favor)” or “no (against)”. Vote results are presented in aggregate, and only members of the UM-KECC team are aware of how each member voted.

	First Year Standardized Waitlist Ratio (can be all patients, not just Medicare)	Prevalent Standardized Waitlist Ratio (Medicare only)	Percent of Prevalent Patients Waitlisted (Medicare only)	Percent of Prevalent Patients Waitlisted in Active Status (Medicare only)
Yes (in favor)	12	10	8	9
No (against)	3	5	7	6



Additional feedback from TEP members was sought in the form of free form comments. Themes included concerns about practitioner attribution and accuracy using the CMS-2728 form; limitations of a Medicare FFS-only population and the need for inclusion of Medicare Advantage patients given the anticipated shifts from Medicare FFS to MA; inclusion of patients listed or transplanted prior to ESRD; crediting practitioners for patients who are transplanted preemptively; anticipated adjustments at the transplant center-level for factors such as local organ supply, geography, average waiting time, and patient characteristics; recognizing the transplant process as not simply an incident event, but a process beyond the first year; pairing of incident and prevalent measures as well as waitlist measures with referral measures to mitigate unintended consequences; emphasis of the importance of active status on waitlisted patients without burden on dialysis facilities that have no control over this status; and proliferation of health inequities and disparities by encouraging facilities to be motivated by “payment over practice.”

Transplant Referral

Introduction

There was substantial support by the TEP for potential measures related to transplant referral, given this process was viewed to be under control of dialysis practitioners. A known barrier to development of such measures was the unavailability of a national data collection mechanism, although pilot and regional efforts at such collection have occurred and are ongoing, in some regions of the country. The TEP reviewed these efforts with a view to clarifying elements of data relating to referral that may be needed to construct potential future practitioner referral measures. The TEP also discussed the possible specifications of such measures in the event that national data collection begins.

Review of prior and current efforts at data collection for transplant referral

Dr. Shahinian started by providing an overview of pilot work previously done by the UM-KECC team under a CMS contract to examine feasibility of data collection on the referral and evaluation process by dialysis facilities. This endeavor included consideration for such data collection to occur using the CROWNWeb platform, a web-based system that dialysis facilities currently use to report certain aspects related to the care of dialysis patients. Ultimately, the pilot study was conducted at two facilities from one dialysis organization between the years 2017-2018. The study took a snapshot at a single point in time at a facility with its existing prevalent patients to identify who had been referred, and to identify where patients were currently in the process (i.e. undergoing evaluation, completed evaluation, waitlisted, decision not to waitlist, etc.). In debriefing sessions held with dialysis facility staff the overall sense was that such data collection was feasible, but that there were challenges with identifying historic referrals (i.e. prior referrals in years past), and finding out where some patients stood with respect to their status from the transplant center's perspective (i.e. those who had been referred, but not evaluated, or were in various stages of completing an evaluation).

Dr. Patzer then described her longstanding regional work collecting transplant referral information. Her work started with the Southeastern Kidney Transplant Coalition, a grassroots organization formed in 2011 in Georgia, North Carolina, and South Carolina, due to the low rates of transplantation among patients with kidney disease in that region. Partners included patients, dialysis facilities, transplant centers, patient advocacy organizations, and large dialysis organizations. The mission of this group is improving access to kidney transplantation and reducing inequities in transplant access. In doing a needs assessment of the community and region very early on, they realized that there was not enough data on transplant referral and some of the early steps in the transplant process. The Southeastern Kidney Transplant Coalition first started as a pilot in Georgia, so Dr. Patzer noted that some of the data presented is focused on just the state of Georgia and the three adult transplant centers that are in Georgia. Later, the data was expanded to the entire network, and the nine adult transplant centers in the three states. ESRD Network 6 functioned as the data coordinating center, but the transplant centers submitted data about patients referred to their program and collected selected fields in the data registry that are not captured in surveillance data. For the most part, the data was accessible in their electronic medical records (EMR). Using EMR systems such as Epic or Cerner, centers are able to run a query and submit this data or pull this data for a particular time period and then submit this upload into a REDCap form, which the data coordinating center received in a secure system; this is the same system that they can securely collect other information from dialysis facilities and other sources that are CMS-approved. There is some amount of data processing that the ESRD network completes, including quality checks for missing data, backfilling, and linking to other data sources. Data is linked to the United States Renal Data Systems to check for validity issues that may arise of patients referred outside of the region. Furthermore, the group wanted to have information about patients who were not referred to create the denominator for the transplant program. This data is referred to as the Early Transplant Access Registry Data and has been used for a number of different research questions and development of quality measures. Those are available at both the patient and facility levels. The data that is being presented includes only 9 of the more than 250 transplant centers across the country.

A TEP member asked whether they collected the referring physician or just the dialysis facility; Dr. Patzer noted that in the past they had not collected the referring provider number and suggests that this be a point of discussion for the TEP. This information is included on most people's referral form and may be important to capture for a practitioner level measure. In terms of feasibility, the group has now expanded to three additional ESRD regions after receiving NIH funding in 2019. The goal was 48 transplant centers and about 1800 dialysis facilities; COVID slowed down this process, as they currently have data for 28 transplant centers and about 1000 dialysis facilities. Overall, they estimate about four hours of time for a transplant program to set up the query and to submit the data; for Network 6, this has been a regular data submission, twice yearly, since 2012, and takes established transplant centers about 15 minutes to complete. Challenges include the issue of historic referrals and capturing prevalent patients who were referred prior to the point of data collection. This can occur when the EMR is changed over and they do not have retrospective data captured in the same system. They have good data on prospective referrals and moving forward, this becomes less of a challenge.

Dr. Patzer also noted that several committees within the United Network for Organ Sharing (UNOS) are working on a proposal that would collect transplant referral data nationally and there is a working group being formed. Dr. Patzer provides full disclosure that she is the Data Advisory Committee Chair for UNOS and working on this proposal. Additionally, the Scientific Registry for Transplant Recipients (SRTR) has a new contract from the Health Resources and Services Administration (HRSA) that includes a task to focus on developing some new transplant center quality measures. Their goal is to identify metrics to assess transplant center performance, with a greater focus on incentivizing higher transplant rates. This is an important area for the TEP to consider and this is the first time that HRSA has specifically mentioned pre-waitlisting as an area where they are open to consideration for new quality measures on the transplant program side.

Data presentation on prototype referral dialysis facility measure: Standardized Transplant Referral Ratio

As a way to assist the TEP in its discussion of possible practitioner referral measures, Dr. Patzer presented her previously published work describing a potential dialysis facility measure, the standardized transplantation referral ratio. The measure is structured similarly to the SWR, but representing the observed over the expected number of referrals based on an adjusted model. The measure represents 249 dialysis facilities in Georgia, and is constructed as follows:

- The numerator is the observed number of first referrals to the transplant center within the first year after initiation of dialysis.
- The expected number of first referrals is calculated based on a Cox proportional hazards model, including a number of adjustments.
- Patients older than 70 years were excluded to match the standardized transplant ratio. Facilities with fewer than 5 incident patients per year were excluded.
- Risk adjustment included comorbidities such as BMI, age, sex, and race. Since facility attribution can change within the first year, time at risk was calculated for each facility.

Of note, there was substantial facility level variation in the standardized referral ratio. Slides in Appendix E provide more details as to the measure results.

Dr. Patzer also commented on the source of information for referral, noting that this was based on receipt of a referral from the transplant center. Based on work comparing reporting of referrals by dialysis facilities versus transplant centers showing some discordance, the decision was made to use receipt of referral by the transplant center as the gold standard.

Finally, to examine validity of the dialysis facility referral measure, it was correlated with a number of other transplant related outcomes such as the percent of patients informed of transplant options, pre-ESRD nephrology care, waitlisting, and transplantation; however, the referral measure was not associated with most other non-transplant quality indicators such as mortality, hospitalization, anemia management, and flu vaccination rates.

Discussion of a potential practitioner transplant referral measure

Data elements and structure of measure

The TEP discussed the minimum data elements needed to be captured to construct a measure. One suggestion with broad agreement was the date a referral was received by the transplant center to confirm two-way communication between dialysis facilities and transplant centers, similar to work done by Dr. Patzer's group. In terms of modeling structure, a time to event framework was deemed appropriate to encourage earlier referral within the measurement period. A point of substantial discussion was the question of which patients should be in the denominator with regards to a prior history of referral. Some TEP members supported examining for a new referral in patients without a referral within the prior year, although there wasn't consensus on this point. Some members were concerned that the process of evaluation following referral can drag on beyond one year. Another TEP member felt it was important that referrals sent prior to initiation of dialysis should also be accounted for. The challenges of capturing historical referral data was raised, although it was also acknowledged that this was likely to become progressively easier if and when a national data collection mechanism for prospectively identifying new referrals is established.

There was also discussion around whether the measure should be structured around the first year after initiation of dialysis versus inclusive of the first year and beyond. While acknowledging the importance of incentivizing referral as soon as possible, several TEP members expressed concern with limiting the measure to the first year alone. Issue raised included the fact that many patients may not be ready for referral within the first year for health or psychological reasons, and referrals may be increasingly done later in the course given the urgency for waitlisting is not as acute following the new Kidney Allocation System.

Adjustments and exclusions

The TEP discussion moved to possible adjustments and exclusions, with one issue raised being whether reasons for non-referral from the dialysis facility side should be captured and incorporated into the measure. A number of TEP members felt it was the transplant center's responsibility to ultimately determine a patient's appropriateness for transplant candidacy, and that there were few absolute contraindications to referral. A contrasting concern raised was that indiscriminate referral of most patients could have the unintended consequence of overwhelming transplant centers. Overall there was therefore broad support for social risk and medical risk adjustment for the referral measures to incentivize appropriate referrals, and to account for variation in transplant center criteria for candidate consideration. Another point raised by TEP members included the importance of properly educating patients prior to referral, but it was unclear how to capture this validly for incorporation into a potential referral measure.

Other Considerations

The TEP members discussed several additional relevant points regarding potential referral measures. One point had to do with the value of referral vs waitlisting measures. Although there was broad agreement that referral was more clearly under the control of dialysis practitioners than waitlisting, a number of TEP members were concerned that referral alone was a low bar. In particular, this was supported by Dr. Patzer's work showing that even after referral, a minority of patients move on to evaluation and further steps towards waitlisting. There was some discussion that future measures could also examine progress from referral towards waitlisting, particularly if the necessary data elements were collected as part of national surveillance data.

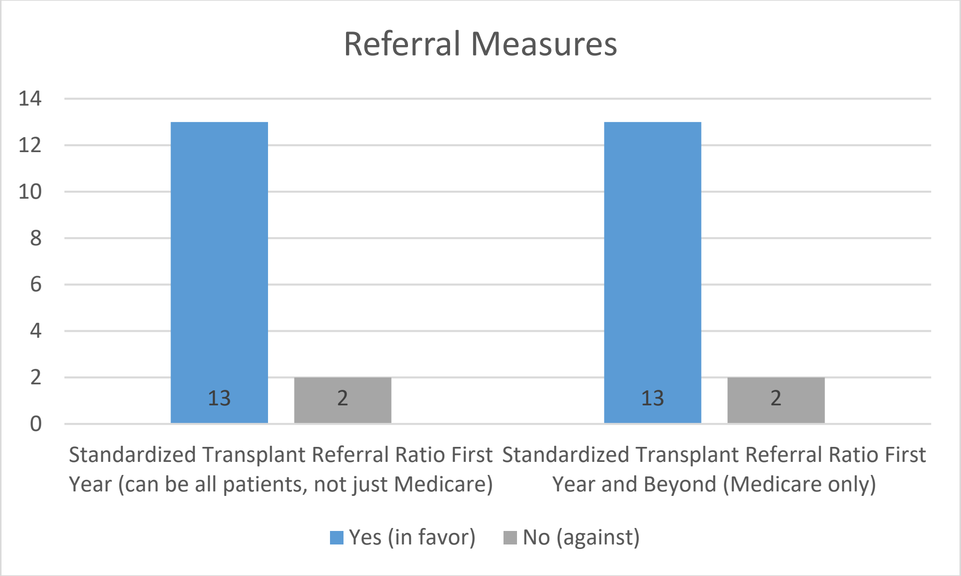
A TEP member brought up the importance of measuring referral prior to initiation of dialysis, as this would help support the possibility of pre-emptive transplantation, the optimal outcome for patients with advanced kidney disease.

Similar to the waitlisting measure, there was also discussion of how referral measures could be utilized to improve care. In particular, it was deemed valuable to provide feedback to practitioners on their performance (unadjusted) relative to peers, to allow them to develop strategies to improve the care they delivered. On the other hand, adjustment for social risk and other factors may be necessary for measures implemented as part of pay for performance programs to avoid penalizing practitioners disproportionately providing care to high risk patients.

Voting results and final comments

UM-KECC sought feedback from the TEP at the conclusion of the virtual meetings through a vote on each of the proposed, provisional measures based on discussions held to date by the TEP, recognizing that data needed for referral measures are not yet collected at a national level. The input served as the foundation for the subsequent, ongoing development work and strategy for measure specifications for the referral measures. Individual TEP members were asked, "Please indicate whether you support continued development of the following referral measures" with the options of "yes (in favor)" or "no (against)". Vote results are presented in aggregate, and only members of the UM-KECC team are aware of how each member voted.

	First Year Standardized Transplant Referral Ratio (can be all patients, not just Medicare)	Prevalent Standardized Transplant Referral Ratio (Medicare only)
Yes (in favor)	13	13
No (against)	2	2



Additional feedback from TEP members was sought in the form of comments. Themes included limitations of a Medicare FFS-only population; the need for a clear, standardized definition for referral; ensuring high quality referrals that include more information than patient name and date of referral receipt; ensuring evaluation of readiness for referrals (i.e. routine healthcare maintenance, age-appropriate cancer screening and dental care are current, BMI criteria); engaging referring providers to help meet goals for transplant eligibility as part of their efforts to facilitate transplant access for their patients; ensuring that engagement with specialists for key chronic conditions is current; unintended consequences of overloading the system with “low quality” referrals that consume transplant practitioner effort, are unlikely to lead to transplant, and thus divert resources for the evaluation of more suitable patients; pairing of waitlist measures with referral measures to mitigate unintended consequences; an education measure that will hold centers accountable for more quality referrals; patient education as a part of the referral process; variation in exclusion criteria across transplant centers; use of the CMS-2728 form for attribution of practitioners; counting preemptive transplants in the numerator and denominator; adequate risk adjustment to avoid inappropriately penalizing practitioners who care for at-risk populations; empowering patients to exert more control over their own health outcome; efficiency of waitlisting and evaluation; and adequate risk-adjustment.

Transplant Education

Discussion during TEP deliberations

As acknowledged early in the TEP discussions, no valid source of national data on delivery of high quality transplant education is available. Given this, the TEP did not specifically discuss measures related to transplant education. Nevertheless, the importance of educating patients on the transplantation option was a common thread throughout discussions on the waitlisting and referral measures. A number of patient TEP members reflected on their own experiences. For example, one TEP member recalled their experience following a new diagnosis of ESRD, where a number of issues relevant for dialysis were discussed, such as vascular access preparation, but the option of transplantation was not presented or discussed in the initial orientation. They ultimately had to use their own initiative to seek out information about kidney transplantation, and be eventually referred to a transplant center. The TEP member concluded that even at the beginning stage of the orientation, all of the information should be presented, giving the patient the opportunity before saying “no” to a workup or evaluation,. This TEP members and others supported the importance of early education about the transplantation option, even for those patients not yet ready to proceed with a transplant referral and evaluation. Another TEP member noted that the CMS conditions for coverage require the dialysis facility team to annually review options with patients, and that education on transplantation should be periodically reviewed with dialysis patients on an ongoing basis. A final point brought up was the importance of proper education as preparation for referrals and evaluation, and that it may contribute to more optimal downstream outcomes.

TEP feedback survey

Although limited discussion of transplant education occurred during TEP deliberations, Dr. Shahinian remarked that there is potential interest in developing such a measure from CMS. He presented a recently developed patient-reported outcome measure in ongoing development, the Life Goals Survey. Dr. Shahinian sought additional feedback in electronic form from TEP members on the Life Goals Survey, and the potential to either adapt it, or develop something else along similar lines relevant to the concept of transplant education. Comments received are summarized as follows. Members generally gave positive reviews of the Patient Life Goals Survey and acknowledged that life goals are important in patient care and valuable to understand. One TEP member asserted that completion of the transplant evaluation process could itself be viewed as a measure of the effectiveness of transplant education. The member also suggested the development of a patient survey that measures or ranks which renal replacement therapy options would be the best for them and their lifestyle. Another TEP member described adapting the new person-centered primary care measure for dialysis facilities. One member felt that the Life Goals survey may be too simplistic, and may not address the needs of younger patients in particular. One patient TEP member described their own experience in which their goals were not discussed until they spoke with a home dialysis nurse. The member found this to be an extremely positive experience and felt that a broadly applied survey about life goals would be valuable for all dialysis patients, including in-center dialysis patients.

A TEP member acknowledged that the Life Goals Survey could be useful to for practitioners to identify what was important for patients, but it wasn't clear whether it would help guide discussion about transplant as a treatment modality. The member suggested including a patient activation scale metric in the survey. The member also suggested development of standardized educational programs, with CMS establishing a credentialing body where all programs could be submitted for accreditation. The credentialing body could establish a set of learning objectives and content topics that have to be included and could be vetted externally to be comprehensive. External review would eliminate many biases and create continuity of education across organizations for patients. After the credentialing body vets the education, if the education passes, the nephrologist would be scored for either having an accredited program or not and would receive either increased or reduced payments for doing this. Nephrologists could also receive payment for their time for preparing and submitting a program for accreditation. After this accredited program is established, then, each nephrologist could be tracked for number of conversations using the accredited program for at least 15 minutes and number of patients who had these conversations with either a nephrologist or his or her designee (e.g., a social worker). Finally, another suggestion was to add a transplant educational statement that could be endorsed and added to the Kidney Disease Quality of Life Instrument (KDQoL) and In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) such as, "In general, patients who get a transplant live longer than those who remain on dialysis for their lifetimes."

Summary of TEP Recommendations

There was strong and uniform support by all TEP members for initiatives directed at improving access to kidney transplantation. Underpinning this sentiment are the known health and quality of life benefits of transplantation over maintenance dialysis for most patients with ESRD, coupled with demonstrably wide variations across dialysis facilities and practices, and persistent disparities, in access to transplantation.

Waitlisting

With respect to the four provisional practitioner level waitlisting measures proposed to the TEP, voting demonstrated majority support for continued development of all of them, although far from unanimous and with variation in the degree of support across the measures. Support for these measures based on TEP discussions reflected the importance of waitlisting, given it is a crucial and necessary step for transplantation and may confer emotional benefits to patients. In addition, dialysis practitioners can directly contribute to processes necessary for eventual waitlisting, such as educating patients about the benefits of transplantation and assisting with referral to transplant centers for evaluation. However, TEP discussions also raised concerns that practitioner level measures may not appropriately reflect quality. This could arise due to differences in the characteristics of patient populations managed by practitioners that could in turn influence the transplant candidacy of patients under their care. As such, robust adjustment of the measures for social risk factors and medical comorbidities was deemed necessary. In addition, factors from the transplant center side (including for example, criteria for waitlisting, or regional organ availability), outside of the control of dialysis practitioners, could also serve to undermine these measures as an adequate reflection of practitioner quality. As such, development of a transplant center adjustment was deemed highly desirable to mitigate these concerns. Such an adjustment could also serve to mitigate another concern raised about the prevalent waitlisting measures wherein dialysis practitioners referring to transplant centers with high transplant rates could seem to be doing poorly as their patients may be more rapidly removed from the waitlist. Another point of concern raised related to the population of patients to which the measures would apply. Given data availability limitations discussed in sections above, only one of the measures, the First Year Standardized Waitlist Ratio would potentially be applicable to all patients, whereas the other three are limited to Medicare Fee-For-Service patients. During deliberations, TEP members expressed a strong preference for measures applicable to the entire population of dialysis patients, to provide a fuller representation of care provided by practitioners. This may have reflected why the First Year Standardized Waitlist Ratio had the strongest support (12 of 15 TEP members in favor, vs 8-10 in favor across the other measures), despite being limited only to the first year after dialysis initiation.

Referral

Voting by the TEP demonstrated strong majority support for the two proposed provisional referral measures. This reflected discussions that referral was a crucial step towards eventual waitlisting and transplantation, and the fact that it was considered to be well within the control of dialysis practitioners. A concern raised in discussions by some members was that referral alone may be too low a bar, given it has been demonstrated that many referred patients do not progress to evaluation and waitlisting. Furthermore, social risk factor and comorbidity adjustment was also deemed necessary, to ensure any such measures reflect practitioner quality and also to avoid incentivizing indiscriminate referral of all patients, which could overwhelm transplant centers. The primary limitation to further development of referral measures is national data availability, although collection of such data is deemed feasible given ongoing regional initiatives. The TEP recommended ongoing efforts to develop a platform for the collection of this data on a national scale. Such data would not only support referral measures, but could also be used to develop additional important measures examining the transition from referral to waitlisting.

Education

The importance of early and high quality education of patients about transplantation was a common thread throughout the TEP discussions. Although important in its own right as one of the first steps towards transplantation, proper education also is likely to increase the success of subsequent steps through referral, evaluation, waitlisting and living donor kidney transplantation. The main challenge at this time is there is no good mechanism or instrument to capture whether high quality education has occurred. For example, evidence of the inadequacy of a simple checkbox such as on the CMS-2728 form was reviewed during the TEP deliberations. Nevertheless the TEP strongly supported further development work in this regard with a view to possible future measures targeting education.

Other Recommendations

Beyond specific measures, the TEP also had several other recommendations.

- The TEP recommended improvements in, or development of systems for, the national collection of a number of data elements to assist with ongoing measure development related to access to transplantation. First, as already mentioned, it was deemed important to develop a national data collection mechanism for transplant referral, but capture of additional downstream events such as initiation of evaluation, and completion of evaluation, would also be highly desirable to track patients through these processes. Second, it would be important to develop collection of data elements necessary for measure construction through methods other than Medicare claims, to obviate a dependence on only examining the Medicare FFS population. This could include, for example, use of the CROWNWeb platform. Relevant data elements could include comorbidity, social risk and responsible dialysis practitioner for attribution purposes. Third, increasing the availability and quality of Medicare Advantage data in particular was deemed important given the rapidly growing of proportion of ESRD patients on dialysis likely to be so insured.

- Although ultimately not deemed to be part of the mandate for this TEP, TEP members nevertheless emphasized that measures directed at patients with advanced chronic kidney disease, prior to initiation of dialysis, were also crucial for improving access to kidney transplantation. These should be a target for future measures, or incorporation into broader measures covering the spectrum of patients from advanced chronic kidney disease prior to dialysis through to beyond initiation of dialysis.
- TEP members also commented on issues pertaining to the potential implementation of the measures. One recommendation was that provision of data on unadjusted performance on the measures by practitioners relative to their peers could assist them with development of mitigating strategies. However, appropriate adjustment would be necessary for measures used in pay for performance programs to potentially avoid penalizing practitioners caring for disproportionately high risk populations of patients. Another recommendation was to consider other ongoing quality initiatives relevant for access to transplant, such as the ETC model, to ensure appropriate harmonization with any measures developed as an output of this TEP's discussions.

Public Comments

The following comments were stated during the TEP deliberations:

Patti Bologna
Thursday, April 15th 2021
"I'm just wondering how other variables that are being taken into consideration when you're talking about reliability and validity something like the self-concept. Self-image of the patient and also maybe a demographic prejudice against transplant and donation. How is that being taken into consideration?"

Elena K Balovlenkov RN, MS
Thursday, April 15th 2021
"I'm a quality improvement director for IPRO free network too, but I'm speaking up as a private citizen. Basically, I'm a nurse who's worked in dialysis since God was the baby. But I don't know if you all were aware that we just did a dedicated change package with CMS specifically aimed at trying to get patients started on the waitlist process, and one of the things that we're looking at is standardizing the education, not just with using handouts, but using videos like high risk kidneys, looking at utilizing trailblazers, the idea of peer-to-peer mentorship, and we've gotten—while the sample sizes were small—we worked with groups within the [inaudible] area. We got pretty good feedback from patients on the tools that they evaluated, to see whether they would be accepted as they were adopted or adapted or rejected. So we are looking at some of that work to try to standardize and you're absolutely correct we're not standing there in the room and education is done. And voice and tone and everything reflect that but I do think that the quality of the resources that we have are getting significantly better like I was very familiar with the work that Dr. Waterman did when I worked at CMS and that's the kind of stuff we're looking for."

Patti Bologna,
Tuesday, May 11th, 2021
"Thank you, I just wanted to make a comment about the criteria for the different facilities. I think I have the session last week, [a TEP member] was saying that she actually found it hard to get listed sort of because of this, because she had lupus. And so, she was turned down in some cases, and had to wait an inordinate amount of time to get waitlisted. I did not become aware of that practice, personally. I was listed at two facilities, one in Ohio and one in Detroit and became aware that they had different criteria. I was not disqualified, but for one to require dental and the other not. I think that in a prior session, and I'm sorry I

don't know which panelist it was, but the gentleman said that he was aware of what different facilities would rule out. And so he, actually, knowing that, referred people to the facilities that would be most amenable to listing them. Also, I think [a TEP member] was talking about an index. I thought that was a very interesting comment, too, and I just think that it would really help patients to be able to be listed and for the success of the nephrologist to list a patient if they made people aware of this, so thank you."

Lisa McGonigal from Kidney Care Partners
Tuesday, May 11th, 2021
I just wanted—it sounded like you're probably going to talk about this on the next call, but I just wondered what the issue is with the referral data point and why that—it seems like that should be something that's fairly easy to capture. I don't know if it was a validity problem, or what the issue is there, because that seems like a pretty important data points."

Patti Bologna
Tuesday, May 25th, 2021
"Thank you. I'm just wondering if the dialysis facility really has the information that the transplant center has. I think Emily was talking about the fact that they require the centers to have the information about requisites for transplant that the different facilities have. Which is something that the dialysis facility couldn't possibly know and again the dialysis facility might also be ruling out some people that are not people that should be ruled out. Just my comment. Thank you." She also asks a question: "I'm wondering what account. How are people followed who are mobile and move out of the area? Is there some continuity as to how they're followed to another center or another transplant facility? This is after a referral."

Patti Bologna
Tuesday, June 15th, 2021
"I just saw a comment flash across my screen from Dr. Waterman and I'm curious how many people would you not have eyes on under the current focus that you're talking about to just focus on Medicare."

Adam Wilk
Tuesday, June 15th, 2021
"Hi everyone thanks, very much for your really rich discussion. Very fruitful to listen to. Related to the question of adjustment for social risk, I was just thinking about those few providers who status would change under a system with versus without social risk; so, people who might shift from above average to at or below average, for example, with versus without adjustment. And while it may be a relatively small number of facilities, whose status actually changes comparing these two types of systems, those kinds of providers that do you see the status change seem to be the kinds of ones that we would want the system to focus on, particularly. So, I'm thinking about, for example, providers who do really well for a high risk population, right? They would be penalized under a system without adjustment and better rewarded under a system with adjustment or, conversely, facilities that do relatively poorly, despite having a low risk population, they might be rewarded under a system without adjustments even though their actions wouldn't really merit that kind of reward. So just from an optics perspective, of course, there will be, like you can reasonably expect, major stories told about both of these types of providers that this group would hate to see told because of the absence of social risk adjustment. But even just more generally, when talking about what is the intent of this whole system, it seems more consistent with the goals of the system to include some form of risk adjustment, rather than to choose not to include one."

Patti Bologna
Thursday, June 17th, 2021
"Thank you. This is vis-à-vis the discussion of adjusting for people who refuse to have transplants. And it was stated previously that there are people that had if they had received education, maybe they would have changed their mind, and I want to tell you my short story: I was under the care of a physician who watched

my GFR plummet from 30 to 14 without ever mentioning transplant or dialysis as an option. When my GFR—and a t that point, I didn't even know what my figures were or understand them—I was told that he wanted to do a kidney biopsy. He said, 'oh, your numbers have descended dramatically.' And, frankly, I was kind of angry—not even kind of—I was, and I said, 'what are you going got do for me?' And I told him my reservations about dialysis and transplant. 'Oh, transplant causes mood swings. Oh, dialysis, I just couldn't do that—that sounds gross to go to a center.' Okay? I dropped him and I went to another physician. The other physician's first words were, 'here is your current situation—your health.' He said, 'you need a transplant and, eventually, you may need to go on dialysis.' I had a living donor and I could have been preemptively transplanted. But instead, this was delaying. And I want to tell you, as a sidebar, that my husband and I actually pursued this and spoke to the head of the department. Not as litigious people, but just as people who wanted to improve the lives for the people that came after us. So, that's my story and I am just saying that with education and I was referred to, you know, a presentation where I learned a lot about it—kidney disease—and the treatments for it. I also think that, actually, some of this could be remedied at the dialysis facility level. And you may say, 'oh the dialysis facility…we're not really talking about that.' But, really, they're employees of the physician. The physician is responsible for the treatment that somebody receives over there. They could have lobby days; they could get presentations on depression; they could give them on public transport; on transplant. There's publications that KPAC has even done, 'Is a Transplant Right for Me?' They could provide this and then people would change their minds and you could survey that too and create your own data that way. And I really don't—I mean just the attendance at a presentation like that, it also shows whether a patient is going to be compliant. So there's another set of data that you have. Anyway, that's my story for what it's worth. Thank you for your time."

Katie Ross-Driscoll
Thursday, June 17th, 2021
"Hi. I'm sorry. I left a comment in the chat and then realized that I'm not part of the panel, so just wanted to reiterate that in the public comment period about adjustment for social risk. I think it's clear that it's really important because social risk is such an important determinant of patient outcomes. But one of the potential issues with adjusting for social risk altogether is that we might obscure within-center disparities that occur by social risk status, so we want to make sure that everybody is receiving equal quality of care, regardless of their social risk. So, one way that we might be able to measure this is by using stratification instead of adjustment. Stratification would take care of differences in patient case mix across facilities. And it would also let us look at differences by social risk within facilities so that we can identify at-risk groups, facilities that are doing really well at caring for their high risk patients, and other potential areas for improvement."

Patti Bologna
Tuesday, June 22nd, 2021
"I just want to thank you for allowing public access for this process. Very interesting. Thank you."

Technical Expert Panel Charter

Project Title: ***Practitioner Level Measurement of Effective Access to Kidney Transplantation***

TEP Expected Time Commitment and Dates:

4 - 6 virtual meetings, each being between 1 to 4 hours long. Meetings are tentatively scheduled in April, 2021 and subsequent meetings in May thru July, 2021.

Meetings will be held virtually, via the Zoom video conferencing platform.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop practitioner-level measures in the area of access to kidney transplantation for dialysis patients. The contract name is Kidney Disease Quality Measure Development, Maintenance, and Support. The contract number is 75FCMC18D0041, task order number 75FCMC18F0001. As part of its measure development process, the University of Michigan Kidney Epidemiology and Cost Center convenes groups of stakeholders who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

Project Objectives:

UM-KECC has been tasked by CMS to develop practitioner level quality measures that allow measurement of patient's access to kidney transplantation. Topic areas may include waitlist, referral, education, and other related issues.

The results of numerous studies have indicated that the recipients of renal transplants have better survival than comparable dialysis patients.[1] The ESRD Conditions for Coverage mandate a comprehensive reassessment of each patient annually (at minimum) with the revision of the Plan of Care. Both the patient assessment and Plan of Care should include reevaluation of treatment modality and transplant status. Specifically, Section 494.80(a)(10) of the revised Conditions for Coverage for ESRD Facilities, effective October 14, 2008, sets forth requirements for patient assessment with regard to transplantation referral: "Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for non-referral must be documented in the patient's medical record."[2] Additionally, objectives CKD-12 and CKD-13 of Healthy People 2020 have the goal to "increase the proportion of dialysis patients wait-listed and/or receiving a deceased donor kidney transplant within 1 year of ESRD start (among patients under 70 years of age)" and "increase the proportion of patients with treated chronic kidney failure who receive a transplant".[3] Substantial variations by facility

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[1] Wolfe RA, Ashby VB, Milford EL, et al. Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant. N Engl J Med. 1999 Dec 2; 341(23):1725-30.

[2] Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule."*Federal Register* 73:73 (15 April 2008) p. 20479.

[3] http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=6

and geographic region, as well as disparities by race and socio-economic status in transplantation rates raise concerns about current processes for provision of access to transplantation.[4]

This work will build on the work of the 2015 TEP, which led to the development of two facility level metrics (the Standardized Waitlist Ratio, and the Percentage of Prevalent Patients Waitlisted).

Technical Expert Panel (TEP) Objectives:

The TEP will use existing data and their expert opinion to formulate recommendations to UM-KECC regarding the development of a draft measure that addresses potentially important quality gaps in access to transplantation. Recommended measures should be evidence based, scientifically acceptable (reliable and valid), feasible, and usable by CMS, providers, and the public.

Specifically, TEP discussions may include, but not be limited to, the following topics:

- Adaptation of the existing facility level transplant waitlist measures to the practitioner level;
- Review of prototype measure for patients active on the waitlist at the facility and practitioner level;
- Considerations for development of transplant education and transplant referral measures at the facility and practitioner level

TEP Requirements:

A TEP of approximately 9-15 individuals will evaluate measure concepts. The TEP will be composed of individuals with differing areas of expertise and perspectives, including:

- Transplant process expertise (from candidate evaluation through to transplantation) including transplant nephrologists, transplant surgeons, social workers, transplant coordinators/nursing;
- Dialysis facility perspective on referral to transplant evaluation including nephrologists, nurses, social workers
- Transplant policy expertise;
- Individuals with consumer/patient/family perspective and consumer and patient advocates; specifically, patients with experience with transplant work-up, time on the waitlist, transplantation and failed transplants
- Individuals with research expertise with Medicare data and issues pertaining to access to kidney transplantation;
- Individuals with perspectives on healthcare disparities in access to transplantation;
- Expertise in performance measurement and quality improvement

Scope of Responsibilities:

UM-KECC is seeking balanced representation of dialysis stakeholders and clinical experts representing patients and patient-advocates, dialysis providers, as well as clinical, statistical, and public health experts to evaluate several aspects of a draft quality measure intended to evaluate effective access to kidney transplantation for dialysis patients. The TEP will also have the opportunity to advance additional measure concepts via brainstorming sessions, as time allows. It is UM-KECC's intent to facilitate TEP

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[4] Patzer RE et al. Dialysis facility and network factors associated with low kidney transplantation rates among United States dialysis facilities. American Journal of Transplantation 14(7):1562-1572.

discussion through presentation of background information and a description of the draft quality measure. The TEP will be led by one or two Chairpersons, whose responsibility is to lead the discussion and attempt to develop consensus opinions from TEP membership regarding the topics described in TEP Objectives section above. The TEP is intended to be advisory to UM-KECC, as UM-KECC continues to develop and refine the draft measure described in this document.

The role of each TEP member is to provide advisory input to UM-KECC.

Role of UM-KECC: As the CMS measure developer contractor, UM-KECC has a responsibility to support the development of quality measures for ESRD patients. The UM-KECC moderators will work with the TEP chair(s) to ensure the panel discussions focus on the review of draft measure specifications, as recommended by the contractor. During discussions, UM-KECC moderators may advise the TEP and chair(s) on the needs and requirements of the CMS contract and the timeline, and may provide specific guidance and criteria that must be met with respect to CMS and NQF review of revised candidate measures reflecting prevalent comorbidities.

Role of TEP chair(s): Prior to the TEP meetings, one or two TEP members are designated as the chair(s) by the measure contractor.. The TEP chair(s) are responsible, in partnership with the moderator, for directing the TEP to meet the expectations for TEP members, including provision of advice to the contractor regarding measure specifications.

Duties and Role of TEP members: According to the CMS Measure Management System Blueprint, TEPs are advisory to the measure contractor. In this advisory role, the primary duty of the TEP is to review any existing measures, provide input as to data sources and feasibility, and to suggest measure specifications. TEP members are expected to attend conference calls in 2021 and be available for additional follow-up teleconferences and correspondence as needed in order to support the submission and review of the candidate measure(s) by NQF. Some follow up activities may be needed after testing has occurred.

The TEP will review, edit (if necessary), and adopt a final charter at the first teleconference. A discussion of the overall tasks of the TEP and the goals/objectives of the ESRD Facility Level Measure Development project will be described. TEP members will be provided with a summary of peer reviewed literature and other related quality measures. TEP members will have the opportunity to submit additional studies to be included in the literature review. A review of the CMS and NQF measure development criteria will also be covered during the teleconference.

During the TEP Meetings: The TEP will review evidence to determine the basis of support for proposed measure(s). The key deliverables of the TEP include:

- Recommending draft measure specifications
- Assisting in completing the necessary documentation forms to support submission of the measures to CMS for review, and to the NQF for endorsement
- As needed TEP members may be asked to provide input to UM-KECC as they prepare responses to NQF and public comments

Following the TEP meetings the TEP chair(s) and TEP members will prepare a summary of recommendations. As necessary, the TEP chair(s) will have additional contact with UM-KECC moderators to work through any other issues. This will include votes for draft and final measures. TEP members will review a summary report of the TEP meeting discussions, recommendations, draft measure specifications, and other necessary documentation forms required for submission to the NQF for endorsement.

Guiding Principles:

Participation as a TEP member is voluntary and the participant's input will be recorded in the meeting minutes, which will be summarized in a report that may be disclosed to the public. If a participant has chosen to disclose private, personal data, then related material and communications are not deemed to be covered by patient-provider confidentiality. Patient/caregiver participants may elect to keep their names confidential in public documents. If they chose to participate anonymously their name and information will not be included on any materials provided to the other TEP members or in the public reports. Additionally – they will be assigned a blinded alias which they will be able to use for all virtual conferencing. UM-KECC will answer any additional questions about confidentiality.

The TEP will use both verbal consensus and formal voting by secret ballot for decision-making, depending on the context of the decision. For administrative and other decisions about agenda, direction of discussion, and other minor operational decisions, informal verbal consensus directed by the TEP chairs will be utilized. In order to objectively record TEP recommendations about the validity of the quality measures presented and recommended changes, formal votes utilizing secret ballot will be employed. These techniques have been used for nearly all of clinical TEPs facilitated by the UM-KECC team over the last several years.

The measures evaluation standards included in the CMS Measures Blueprint and reflected in the National Quality Forum (NQF) criteria are presented during an early TEP teleconference, typically during the first call. This is done so that TEP Charter approval and initial direction of the TEP discussion occur after TEP members are informed of the national consensus criteria that will ultimately be used to evaluate the quality measure(s) being considered by the TEP.

All potential TEP members must disclose any significant financial interest or other relationships that may influence their perceptions or judgment. It is unethical to conceal (or fail to disclose) conflicts of interest. However, the disclosure requirement is not intended to prevent individuals with particular perspectives or strong points of view from serving on the TEP. The intent of full disclosure is to inform the measure developer, other TEP members, and CMS about the source of TEP members' perspectives and how that might affect discussions or recommendations.

Estimated Number and Frequency of Meetings:

4 - 6 virtual meetings, each being between 1 to 4 hours long. Meetings are tentatively scheduled in April 2021 and subsequent meetings in May thru July 2021.

Date Approved by TEP:

TBD

TEP Membership:

TBD

Technical Expert Panel Membership List

Project Title: ***Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel.***

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop practitioner-level measures in the area of access to kidney transplantation for dialysis patients. The contract name is Kidney Disease Quality Measure Development, Maintenance, and Support. The contract number is 75FCMC18D0041, task order number 75FCMC18F0001. As part of its measure development process, the University of Michigan Kidney Epidemiology and Cost Center convenes groups of stakeholders who contribute direction and thoughtful input to the measure developer during measure development and maintenance. UM-KECC has been tasked by CMS to develop practitioner level quality measures that allow measurement of patient's access to kidney transplantation. Topic areas may include waitlist, referral, education, and other related issues.

TEP Membership:

We have selected these individuals and they have agreed to serve as the TEP for this project:

Name, Credentials, Professional Role*	**Organizational Affiliation, City, State***	**Consumer/ Patient/ Family/ Caregiver Perspective***	***Clinical Content***	***Performance Measurement***	***Coding and Informatics***	**Conflict of Interest Disclosure***
David Axelrod, MD, MBA, Transplant Surgeon	University of Iowa Iowa City, IA		X	X		Consulting arrangements with CareDx and Talaris; active research into outcomes after kidney and liver transplant using linked datasets.
Amy Waterman, PhD, Professor of Medicine, Nephrology	UCLA Nephrology Los Angeles, CA		X	X	X	
Bobby Howard, Patient, Director, Multicultural Donation Education Program	LifeLink of Georgia Association of Organ Procurement Norcross, GA	X				
Jesse Schold, Mstat, PhD, Research Director	Cleveland Clinic Chagrin Falls, OH		X	X	X	
Emily Watson, MSW, LCSW, Social Worker	Satellite Healthcare, LLC San Jose, CA		X			

Name, Credentials, Professional Role*	Organizational Affiliation, City, State*	Consumer/ Patient/ Family/ Caregiver Perspective*	*Clinical Content*	*Performance Measurement*	*Coding and Informatics*	Conflict of Interest Disclosure*
Krista Lentine, MD, PhD Professor of Medicine	American Society of Nephrology Policy & Advocacy Committee Saint Louis University ASN Alliance for Kidney Health St. Louis, MO		X			CareDx, consulting. Sanofi, speakers bureau.
Bryan N. Becker, MD, MMM, Physician	DaVita, Inc. Hinsdale, IL		X			Employed by DaVita, Inc., and own DaVita, Inc. stock.
John T. Ducker, MD, Transplant Nephrologist	Nephrology Associates of Northern Illinois and Indiana Renal Physicians Association Ft. Wayne, IN		X			
Teri Browne, PhD, MSW, Associate Dean and Professor	University of South Carolina College of Social Work Irmo, SC		X	X		
Rachel Patzer, PhD, MPH, Director, Health Services Research Center	Emory University School of Medicine Atlanta, GA		X	X		
Della Major, MA , Patient	National Forum of ESRD Networks, member of the Kidney Patient Advisory Council Chicago, IL	X				
Sumit Mohan, MD, MPH, Physician and Epidemiologist	Columbia University American Society of Nephrology Alliance for Kidney Health Irvington, NY		X	X		
Dawn P. Edwards, Patient	National Forum of ESRD Networks Kidney Patient Advisory Council Jamaica, NY	X				
Geraldine Zingraf, DNP, MBA, RN, CNN, CCTC, Transplant Administrator	Edward Hines, Jr. VA Hospital Franklin Park, IL		X			
Sasha Couch, Patient	Renal Support Network Los Angeles, CA	X				

Kidney Disease Quality Measure Development, Maintenance, and Support

Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel
Annotated Bibliography

Contents

Overview

UM-KECC's Literature Review and Environmental Scan supporting access to kidney transplantation quality measures began in February 2021. A series of searches were undertaken iteratively to identify pertinent PubMed content relating to the three steps in the transplant process: referrals, waitlist, and receiving a transplant. Search results were screened for general topic applicability prior to a focused review by two clinical investigators associated with the workgroup. Also included in the environmental are existing guidelines and measures relating to access to kidney transplantation for CKD and ESRD patients.

Literature Review Summary

A preliminary PubMed search in February, 2021 limited to articles published in the English language since January 6th, 2015 (the end date for the literature search performed for the prior Access To Transplantation TEP) was conducted with the following search criteria: ("kidney transplantation"[All Fields] OR "kidney transplant"[All Fields] OR "renal transplant"[All Fields] OR "renal transplantation"[All Fields]) AND ("referral"[All Fields] OR "access"[All Fields] OR "disparities"[All Fields] OR "waitlist"[All Fields]) AND ("2015/01/06"[PDat] : "2021/01/31"[PDat] AND "humans"[MeSH Terms] AND English[lang]). A total of 1,107 articles were initially identified. The titles and a brief abstract review of the articles was performed to further limit them to those focusing more closely on access to transplantation and in particular, within the U.S. system.

The references identified through the above literature search processes were merged and duplicates were deleted, resulting in a master list of 176 articles. A more comprehensive review investigating the relevance of each article generated a condensed list of approximately 63 articles to be included in the annotated bibliography for the access to kidney transplantation technical expert panel. In addition, the 60 articles identified as part of the prior Access to Transplantation TEP were reviewed, with 7 selected for inclusion in the current bibliography. Finally, the U.S. Department of Health & Human Services Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program was included as an additional reference.

**Citations that are preceded by an asterisk are indicative of recommendation by a member of the Access to Kidney Transplantation Technical Expert Panel and as such were incorporated in to the bibliography after UM-KECC's initial literature scan.*

Annotated Bibliography

Amaral S, Sayed BA, Kutner N, Patzer RE. **Preemptive kidney transplantation is associated with survival benefits among pediatric patients with end-stage renal disease.** *Kidney Int. 2016 Nov;90(5):1100-1108. doi: 10.1016/j.kint.2016.07.028. Epub 2016 Sep 18.*

> **PMID:** 27653837.
>
> **Abstract:** Kidney transplantation is the preferred treatment for pediatric end-stage renal disease (ESRD). Preemptive transplantation avoids the increased morbidity and mortality of dialysis. Yet, previous studies have not demonstrated significant graft or patient survival benefits for children undergoing transplantation preemptively versus nonpreemptively. These previous studies were limited by small samples sizes and low rates of adverse events. Here we compared graft failure and mortality rates using Kaplan-Meier methods and Cox regression among a large national cohort of children with ESRD undergoing preemptive versus nonpreemptive kidney transplantation between 2000 and 2012. Among 7527 pediatric kidney transplant recipients in the United States Renal Data System, 1668 underwent preemptive transplantation. Over a median 4.8 years follow-up, 1314 experienced graft failure, and over a median 5.2 years of follow-up, 334 died. Dialysis exposure versus preemptive transplantation conferred a higher risk of graft failure (hazard ratio 1.32; 95% confidence interval: 1.10-1.56) and a higher risk of death (hazard ratio 1.69; 95% confidence interval: 1.22-2.33) in multivariable analysis. Compared with children undergoing preemptive transplantation, children on dialysis for >1 year had a 52% higher risk of graft failure and those on dialysis >18 months had an 89% higher risk of death, regardless of donor source. Thus, preemptive transplantation is associated with substantial benefits in allograft and patient survival among children with ESRD, particularly when compared with children who receive dialysis for >1 year. These findings support policies to promote early access to transplantation and avoidance of dialysis for children with ESRD whenever feasible.

Balhara, K S & Kucirka, L M & Jaar, B G & Segev, D L **Disparities in provision of transplant education by profit status of the dialysis center.** *Am J Transplant. 2012 Nov;12(11):3104-10. doi: 10.1111/j.1600-6143.2012.04207.x. Epub 2012 Aug 6.*

> **Notes:** Survey of 906 practicing nephrologists attitudes regarding transplant education. Provides some insight about nephrologist opinions about the optimal time required to discuss transplantation with patients and how frequently they did so. Also differences between not-for-profit and for-profit facility nephrologists.
>
> **PMID:** 22883444.
>
> **Abstract:** Kidney transplant education is associated with higher transplantation rates; however national policies regarding optimal timing and content of transplant education are lacking. We aimed to characterize nephrologists' attitudes regarding kidney transplant education, and to compare practices between nephrologists at for-profit and nonprofit centers. We surveyed 906 nephrologist practicing in the United States. Most respondents (81%) felt the ideal time to

spend on transplant education was >20 min, but only 43% reported actually doing so. Spending >20 min was associated with covering more topics, having one-on-one and repeated conversations, involving families in discussions and initiating discussions at CKD-stage 4. Providers at for-profit centers were significantly less likely to spend >20 min (RR = 0.89, 95%CI: 0.80-0.99) or involve families (RR = 0.57, 95%CI: 0.38-0.87); they reported that fewer of their patients received transplant counseling (RR = 0.58, 95%CI: 0.37-0.96), initiated transplant discussions (RR = 0.58, 95%CI: 0.38-0.88), or were eligible for transplantation (RR = 0.45, 95%CI: 0.30-0.68). Of nephrologists who spent ≤20 min, those at for-profit centers more often cited lack of reimbursement as a reason (30.0% vs. 18.9%, p = 0.02). Disparities in quality of education at for-profit centers might partially explain previously documented disparities in access to transplantation for patients at these centers. National policies detailing the optimal timing and content of transplant education are needed to improve equity.

Basu M, Petgrave-Nelson L, Smith KD, Perryman JP, Clark K, Pastan SO, Pearson TC, Larsen CP, Paul S, Patzer RE. **Transplant Center Patient Navigator and Access to Transplantation among High-Risk Population: A Randomized, Controlled Trial.** *Clin J Am Soc Nephrol. 2018 Apr 6;13(4):620-627. doi: 10.2215/CJN.08600817. Epub 2018 Mar 26.*

Notes: Randomized trial of patient navigator intervention to improve waitlisting and referral.

PMID: 29581107.

Abstract: Background and objectives: Barriers exist in access to kidney transplantation, where minority and patients with low socioeconomic status are less likely to complete transplant evaluation. The purpose of this study was to examine the effectiveness of a transplant center-based patient navigator in helping patients at high risk of dropping out of the transplant evaluation process access the kidney transplant waiting list.

Design, setting, participants & measurements: We conducted a randomized, controlled trial of 401 patients (n=196 intervention and n=205 control) referred for kidney transplant evaluation (January 2013 to August 2014; followed through May 2016) at a single center. A trained navigator assisted intervention participants from referral to waitlisting decision to increase waitlisting (primary outcome) and decrease time from referral to waitlisting (secondary outcome). Time-dependent Cox proportional hazards models were used to determine differences in waitlisting between intervention and control patients.

Results: At study end, waitlisting was not significantly different among intervention (32%) versus control (26%) patients overall (P=0.17), and time from referral to waitlisting was 126 days longer for intervention patients. However, the effectiveness of the navigator varied from early (<500 days from referral) to late (≥500 days) follow-up. Although no difference in waitlisting was observed among intervention (50%) versus control (50%) patients in the early period (hazard ratio, 1.03; 95% confidence interval, 0.69 to 1.53), intervention patients were 3.3 times more likely to be waitlisted after 500 days (75% versus 25%; hazard ratio, 3.31; 95% confidence interval, 1.20 to 9.12). There were no significant differences in intervention versus control patients who started evaluation (85% versus 79%; P=0.11) or completed evaluation (58% versus 51%; P=0.14); however, intervention patients had more living donor inquiries (18% versus 10%; P=0.03).

Conclusions: A transplant center-based navigator targeting disadvantaged patients improved waitlisting but not until after 500 days of follow-up. However, the absolute effect was relatively small.

Batabyal, Pikli & Chapman, Jeremy R & Wong, Germaine & Craig, Jonathan C & Tong, Allison **Clinical practice guidelines on wait-listing for kidney transplantation: consistent and equitable?.** *Transplantation. 2012 Oct 15;94(7):703-13. doi: 10.1097/TP.0b013e3182637078.*

Notes: Review of available waitlist guidelines (international). May be useful as general background reference.

PMID: 22948443.

Abstract: BACKGROUND: Apparent variability in wait-listing criteria globally has raised concern about inequitable access to kidney transplantation. This study aimed to compare the quality, the scope, and the consistency of international guidelines on wait-listing for kidney transplantation.

METHODS: Electronic databases and guideline registries were searched to December 2011. The Appraisal of Guidelines for Research and Evaluation II instrument and textual synthesis was used to assess and compare recommendations.

RESULTS: Fifteen guidelines published from 2001 to 2011 were included. Methodological rigor and scope were variable. We identified 4 major criteria across guidelines: recipient age and life expectancy, medical criteria, social and lifestyle circumstances, and psychosocial considerations. Whereas some recommendations were consistent, there were differences in age cutoffs, estimated life expectancy (2-5 years), and glomerular filtration rate at listing (15-20 mL/min/1.73 m). Cardiovascular contraindications were broadly defined. Recommended cancer-free periods also varied substantially, and whereas uncontrolled infections were universally contraindicated, human immunodeficiency virus thresholds and adherence to highly active antiretroviral therapy were inconsistent. Most guidelines recommended psychological screening but were not augmented with specific clinical assessment tools.

CONCLUSIONS: Wait-listing recommendations in current guidelines are based on life expectancy, comorbidities, lifestyle, and psychosocial factors. Some recommendations are different across guidelines or broadly defined. There is a case for developing comprehensive, methodologically robust, and regularly updated guidelines on wait-listing for kidney transplantation.

Boulware LE, Ephraim PL, Ameling J, Lewis-Boyer L, Rabb H, Greer RC, Crews DC, Jaar BG, Auguste P, Purnell TS, Lamprea-Monteleagre JA, Olufade T, Gimenez L, Cook C, Campbell T, Woodall A, Ramamurthi H, Davenport CA, Choudhury KR, Weir MR, Hanes DS, Wang NY, Vilme H, Powe NR. **Effectiveness of**

informational decision aids and a live donor financial assistance program on pursuit of live kidney transplants in African American hemodialysis patients. *BMC Nephrol. 2018 May 3;19(1):107. doi: 10.1186/s12882-018-0901-x.*

PMID: 29724177.

Abstract: Background: African Americans have persistently poor access to living donor kidney transplants (LDKT). We conducted a small randomized trial to provide preliminary evidence of the effect of informational decision support and donor financial assistance interventions on African American hemodialysis patients' pursuit of LDKT.

Methods: Study participants were randomly assigned to receive (1) Usual Care; (2) the Providing Resources to Enhance African American Patients' Readiness to Make Decisions about Kidney Disease (PREPARED); or (3) PREPARED plus a living kidney donor financial assistance program. Our primary outcome was patients' actions to pursue LDKT (discussions with family, friends, or doctor; initiation or completion of the recipient LDKT medical evaluation; or identification of a donor). We also measured participants' attitudes, concerns, and perceptions of interventions' usefulness.

Results: Of 329 screened, 92 patients were eligible and randomized to Usual Care (n = 31), PREPARED (n = 30), or PREPARED plus financial assistance (n = 31). Most participants reported interventions helped their decision making about renal replacement treatments (62%). However there were no statistically significant improvements in LDKT actions among groups over 6 months. Further, no participants utilized the living donor financial assistance benefit.

Conclusions: Findings suggest these interventions may need to be paired with personal support or navigation services to overcome key communication, logistical, and financial barriers to LDKT.

Browne T, Patzer RE, Gander J, Amamoo MA, Krisher J, Sauls L, Pastan S. **Kidney transplant referral practices in southeastern dialysis units.** *Clin Transplant. 2016 Apr;30(4):365-71. doi: 10.1111/ctr.12693. Epub 2016 Feb 12.*

PMID: 26782140.

Abstract: Background: The Southeastern Kidney Transplant Coalition was created in 2010 to improve kidney transplant (KTx) rates in Georgia, North Carolina, and South Carolina. To identify dialysis staff-reported barriers to transplant, the Coalition developed a survey of dialysis providers in the region.

Methods: All dialysis units in the ESRD Network (n = 586) were sent a survey to be completed by the professional responsible for helping patients get transplants.

Results: One staff member at almost all (n = 546) of the dialysis units in Network 6 completed the survey (93% response rate). Almost all respondents reported being very comfortable (51.47%) or comfortable (46.89%) discussing the KTx process with patients. Just over half (56%)

of facilities reported discussing KTx as a treatment option with patients on an annual basis. Fewer than one quarter of respondents (19%) perceived that more than 50% of their patients were interested in kidney transplant, and most of the staff surveyed (68%) reported that <25% of their dialysis patients completed the evaluation process and been wait-listed for a kidney transplant.

Conclusion: The survey results provide insight into KTx referral practices in southeastern dialysis units that may be contributing to low KTx rates in this region.

Cervantes L, Hasnain-Wynia R, Steiner JF, Chonchol M, Fischer S. **Patient Navigation: Addressing Social Challenges in Dialysis Patients.** *Am J Kidney Dis. 2020 Jul;76(1):121-129. doi: 10.1053/j.ajkd.2019.06.007. Epub 2019 Sep 9.*

PMID: 31515136.

Abstract: Members of racial and ethnic minority groups make up nearly 50% of US patients with end-stage kidney disease and face a disproportionate burden of socioeconomic challenges (ie, low income, job insecurity, low educational attainment, housing instability, and communication challenges) compared with non-Hispanic whites. Patients with end-stage kidney disease who face social challenges often have poor patient-centered and clinical outcomes. These challenges may have a negative impact on quality-of-care performance measures for dialysis facilities caring for primarily minority and low-income patients. One path toward improving outcomes for this group is to develop culturally tailored interventions that provide individualized support, potentially improving patient-centered, clinical, and health system outcomes by addressing social challenges. One such approach is using community-based culturally and linguistically concordant patient navigators, who can serve as a bridge between the patient and the health care system. Evidence points to the effectiveness of patient navigators in the provision of cancer care and, to a lesser extent, caring for people with chronic kidney disease and those who have undergone kidney transplantation. However, little is known about the effectiveness of patient navigators in the care of patients with kidney failure receiving dialysis, who experience a number of remediable social challenges.

Chadban SJ, Ahn C, Axelrod DA, Foster BJ, Kasiske BL, Kher V, Kumar D, Oberbauer R, Pascual J, Pilmore HL, Rodrigue JR, Segev DL, Sheerin NS, Tinckam KJ, Wong G, Knoll GA. **KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation.** *Transplantation. 2020 Apr;104(4S1 Suppl 1):S11-S103. doi: 10.1097/TP.0000000000003136.*

Notes: Recent KDIGO practice guidelines on evaluation of kidney transplant candidates.

PMID: 32301874.

Abstract: The 2020 Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation is intended to assist health care professionals worldwide who evaluate and manage potential candidates for deceased or living donor kidney transplantation. This guideline addresses general candidacy issues such as access to transplantation, patient demographic and health status factors, and immunological and psychosocial assessment. The roles of various risk factors and comorbid conditions governing an individual's suitability for transplantation such as adherence, tobacco use, diabetes, obesity, perioperative issues, causes of kidney failure, infections, malignancy, pulmonary disease, cardiac and peripheral arterial disease, neurologic disease, gastrointestinal and liver disease, hematologic disease, and bone and mineral disorder are also addressed. This guideline provides recommendations for evaluation of individual aspects of a candidate's profile such that each risk factor and comorbidity are considered separately. The goal is to assist the clinical team to assimilate all data relevant to an individual, consider this within their local health context, and make an overall judgment on candidacy for transplantation. The guideline development process followed the Grades of Recommendation Assessment, Development, and Evaluation (GRADE) approach. Guideline recommendations are primarily based on systematic reviews of relevant studies and our assessment of the quality of that evidence, and the strengths of recommendations are provided. Limitations of the evidence are discussed with differences from previous guidelines noted and suggestions for future research are also provided.

Crenesse-Cozien N, Dolph B, Said M, Feeley TH, Kayler LK. **Kidney Transplant Evaluation: Inferences from Qualitative Interviews with African American Patients and their Providers.** *J Racial Ethn Health Disparities. 2019 Oct;6(5):917-925. doi: 10.1007/s40615-019-00592-x. Epub 2019 Apr 24.*

PMID: 31020606.

Abstract: Background: Completing pre-transplant evaluation is often a barrier to kidney waiting list placement among African American (AA) patients. Interventions are needed to provide AAs with culturally sensitive, understandable information that increases their capacity to achieve placement on the kidney transplant waiting list. Research about enabling and constraining factors for patients to complete the waitlisting process is necessary to inform such interventions; however, few such studies have been conducted specific to AA patient needs.

Methods: Semistructured qualitative focus groups and interviews were conducted with 24 AA listed or transplanted patients (along with their caregivers when available) and 14 transplant providers to explore thoughts, feelings, and assumptions about transplant evaluation. Questions also probed participants' perceptions of enabling and constraining factors to wait-listing. Interviews were recorded and transcribed and inductive thematic analysis was performed to inform message content for a future educational video intervention.

Results: Three themes emerged from thematic content analysis: (1) transplant center support in navigating steps to wait-listing, (2) provider attitude and messaging, and (3) education about evaluation and the waiting list. Enabling factors for evaluation completion included staff assistance with completing testing, frequent communication, and positive staff messaging. Constraining factors were staff inaccessibility, patient scheduling difficulties, and misunderstanding/misinformation regarding the role of the transplant coordinator, process of and requirements for listing, and understanding allocation.

Conclusions: We identified information based on patients' expressed needs and experiences managing evaluation completion. These findings are valuable in efforts going forward to empower AAs to achieve placement on the waiting list.

DuBay DA, MacLennan PA, Reed RD, Shelton BA, Redden DT, Fouad M, Martin MY, Gray SH, White JA, Eckhoff DE, Locke JE. **Insurance Type and Solid Organ Transplantation Outcomes: A Historical Perspective on How Medicaid Expansion Might Impact Transplantation Outcomes.** *J Am Coll Surg. 2016 Oct;223(4):611-620.e4. doi: 10.1016/j.jamcollsurg.2016.07.004. Epub 2016 Jul 25.*

PMID: 27457252.

Abstract: Background: The number of Medicaid beneficiaries has increased under the Affordable Care Act, improving access to solid organ transplantation in this disadvantaged patient cohort. It is unclear what impact Medicaid expansion will have on transplantation outcomes. We performed a retrospective cohort analysis to measure the frequency and variation in Medicaid transplantation and post-transplantation survival in Medicaid patients.

Study design: Adult heart, lung, liver, and renal transplant recipients between 2002 and 2011 (n = 169,194) reported to the Scientific Registry of Transplant Recipients were identified. Transplant recipients were classified based on insurance status (private, Medicare or Medicaid). Outcomes measures included 5-year post-transplantation survival, summarized using Kaplan-Meier curves and compared with log-rank tests. Organ-specific Cox proportional hazards models were used to adjust for donor and recipient factors.

Results: Medicaid patients comprised 8.6% of all organ transplant recipients. Fewer transplantations were performed than expected among Medicaid beneficiaries for all organs except liver (liver: observed to expected ratio = 1.21; 95% CI, 0.68-1.90; heart: observed to expected ratio = 0.89; 95% CI, 0.44-1.49; lung: observed to expected ratio = 0.57; 95% CI, 0.22-1.06; renal: observed to expected ratio = 0.32; 95% CI, 0.08-0.72). Medicaid transplant recipients were listed with more severe organ failure and experienced shorter transplant wait times. Post-transplantation survival was lower in Medicaid patients compared with private insurance for all organs. Post-transplantation survival in Medicaid patients was similar to Medicare patients for heart, liver, and renal but lower in lung.

Conclusions: Medicaid organ transplant beneficiaries had significantly lower survival compared with privately insured beneficiaries. The more severe organ failure among Medicaid beneficiaries at the time of listing, suggested a pattern of late referral, which might account for worse outcomes. Implementation of the Affordable Care Act gives the opportunity to develop the necessary infrastructure to ensure timely transplantation referrals and improve long-term outcomes in this vulnerable population.

Etesami K, Lestz R, Hogen R. **Pediatric kidney transplantation in the United States.** *Curr Opin Organ Transplant. 2020 Aug;25(4):343-347. doi: 10.1097/MOT.0000000000000783.*

PMID: 32692040.

Abstract: Purpose of review: Pediatric kidney transplantation has made great strides over the preceding years. It has become an accepted and successful remedy for thousands of patients worldwide. For best outcomes, it must be viewed and treated as a distinct entity from adult transplantation with focus on the unique challenges particular to its cohort.

Recent findings: Although efforts have been made to decrease geographic disparity and increase allograft access throughout, an unintended consequence has been prolonged wait times for pediatric patients. Concurrently, ideally size-matched organs from older pediatric donors are also being bypassed. Nevertheless, advances in surgical technique and a better understanding of the limits of donor-recipient pairing have facilitated continued usage of adult kidneys for both infants and small for age children. Immunosuppression optimization has meant mean allograft survival measured in decades.

Summary: Enhanced access is needed to better size-matched organs for pediatric recipients, helping diminish wait times for the youngest patients, and improving their long-term prognosis. Longitudinal multicenter studies are needed to help standardize protocols, especially as it relates to optimal surgical and perioperative management. Advances in immunosuppression will continue to enhance patient and graft survival while minimizing adverse effects.

Gander JC, Zhang X, Plantinga L, Paul S, Basu M, Pastan SO, Gibney E, Hartmann E, Mulloy L, Zayas C, Patzer RE. **Racial disparities in preemptive referral for kidney transplantation in Georgia.** *Clin Transplant. 2018 Sep;32(9):e13380. doi: 10.1111/ctr.13380. Epub 2018 Aug 26.*

PMID: 30099781.

Abstract: Background: Racial disparities persist in access to kidney transplantation. Racial differences in preemptive referral, or referral prior to dialysis start, may explain this discrepancy.

Methods: Patient-level data on kidney transplant referrals (2005-2012) from all Georgia transplant centers were linked to the United States Renal Data System to examine racial disparities in preemptive referral, waitlisting, and living donor transplant. Adjusted logistic regression and Cox proportional hazard models determined the associations between race (African American vs white) and preemptive referral, and placement on the waitlist and receipt of a living donor kidney, respectively.

Results: Among 7752 adults referred for transplant evaluation, 20.38% (n = 1580) were preemptively referred. The odds of African Americans being preemptively referred for transplant evaluation were 37% (OR = 0.63; [95% CI: 0.55 0.71]) lower than white patients. Among preemptively referred patients, there was no racial difference (African Americans compared to white patients. HR = 0.96; [95% CI: 0.88, 1.04]) in waitlisting. However, African Americans were 70% less likely than white patients to receive a living donor transplant (HR = 0.30; [95% CI: 0.21, 0.42]).

Conclusion: Racial disparities in transplant receipt may be partially explained by disparities in preemptive referral. Interventions to reduce racial disparities in kidney transplant access may need to be targeted earlier in the disease process.

Gander JC, Zhang X, Ross K, Wilk AS, McPherson L, Browne T, Pastan SO, Walker E, Wang Z, Patzer RE. **Association Between Dialysis Facility Ownership and Access to Kidney Transplantation.** *JAMA. 2019 Sep 10;322(10):957-973. doi: 10.1001/jama.2019.12803.*

PMID: 31503308.

Abstract: Importance: For-profit (vs nonprofit) dialysis facilities have historically had lower kidney transplantation rates, but it is unknown if the pattern holds for living donor and deceased donor kidney transplantation, varies by facility ownership, or has persisted over time in a nationally representative population.

Objective: To determine the association between dialysis facility ownership and placement on the deceased donor kidney transplantation waiting list, receipt of a living donor kidney transplant, or receipt of a deceased donor kidney transplant.

Design, setting, and participants: Retrospective cohort study that included 1 478 564 patients treated at 6511 US dialysis facilities. Adult patients with incident end-stage kidney disease from the US Renal Data System (2000-2016) were linked with facility ownership (Dialysis Facility Compare) and characteristics (Dialysis Facility Report).

Exposures: The primary exposure was dialysis facility ownership, which was categorized as nonprofit small chains, nonprofit independent facilities, for-profit large chains (>1000 facilities), for-profit small chains (<1000 facilities), and for-profit independent facilities.

Main outcomes and measures: Access to kidney transplantation was defined as time from initiation of dialysis to placement on the deceased donor kidney transplantation waiting list, receipt of a living donor kidney transplant, or receipt of a deceased donor kidney transplant. Cumulative incidence differences and multivariable Cox models assessed the association between dialysis facility ownership and each outcome.

Results: Among 1 478 564 patients, the median age was 66 years (interquartile range, 55-76 years), with 55.3% male, and 28.1% non-Hispanic black patients. Eighty-seven percent of patients received care at a for-profit dialysis facility. A total of 109 030 patients (7.4%) received care at 435 nonprofit small chain facilities; 78 287 (5.3%) at 324 nonprofit independent facilities; 483 988 (32.7%) at 2239 facilities of large for-profit chain 1; 482 689 (32.6%) at 2082 facilities of large for-profit chain 2; 225 890 (15.3%) at 997 for-profit small chain facilities; and 98 680 (6.7%) at 434 for-profit independent facilities. During the study period, 121 680 patients (8.2%) were placed on the deceased donor waiting list, 23 762 (1.6%) received a living donor kidney transplant, and 49 290 (3.3%) received a deceased donor kidney transplant. For-profit facilities had lower 5-year cumulative incidence differences for each outcome vs nonprofit facilities (deceased donor waiting list: -13.2% [95% CI, -13.4% to -13.0%]; receipt of a living donor kidney transplant: -2.3% [95% CI, -2.4% to -2.3%]; and receipt of a deceased donor kidney transplant: -4.3% [95% CI, -4.4% to -4.2%]). Adjusted Cox analyses showed lower relative rates for each outcome among patients treated at all for-profit vs all nonprofit dialysis facilities: deceased donor waiting list (hazard ratio [HR], 0.36 [95% CI, 0.35 to 0.36]); receipt of a living donor kidney transplant (HR, 0.52 [95% CI, 0.51 to 0.54]); and receipt of a deceased donor kidney transplant (HR, 0.44 [95% CI, 0.44 to 0.45]).

Conclusions and relevance: Among US patients with end-stage kidney disease, receiving dialysis at for-profit facilities compared with nonprofit facilities was associated with a lower likelihood of accessing kidney transplantation. Further research is needed to understand the mechanisms behind this association.

Grams, M E & Massie, A B & Schold, J D & Chen, B P & Segev, D L **Trends in the inactive kidney transplant waitlist and implications for candidate survival.** *Am J Transplant. 2013 Apr;13(4):1012-1018. doi: 10.1111/ajt.12143. Epub 2013 Feb 7.*

Notes: Observational study describes national trends in waitlisted patients and status (inactive vs. active). In addition, the timing and durability of status changes and association between inactive status and likelihood of eventual transplantation is reported.

PMID: 23399028.

Abstract: In November 2003, OPTN policy was amended to allow kidney transplant candidates to accrue waiting time while registered as status 7, or inactive. We evaluated trends in inactive listings and the association of inactive status with transplantation and survival, studying 262,824 adult first-time KT candidates listed between 2000 and 2011. The proportion of waitlist candidates initially listed as inactive increased from 2.3% prepolicy change to 31.4% in 2011. Candidates initially listed as inactive were older, more often female, African American, and with higher body mass index. Postpolicy change, conversion from initially inactive to active status generally occurred early if at all: at 1 year after listing, 52.7% of initially inactive candidates had been activated; at 3 years, only 66.3% had been activated. Inactive status was associated with a substantially higher waitlist mortality (aHR 2.21, 95%CI:2.15-2.28, p<0.001) and lower rates of eventual transplantation (aRR 0.68, 95%CI:0.67-0.70, p<0.001). In summary, waitlist practice has changed significantly since November 2003, with a sharp increase in the number of inactive candidates. Using the full waitlist to estimate organ shortage or as a comparison group in transplant outcome studies is less appropriate in the current era.

Hamoda RE, McPherson LJ, Lipford K, Jacob Arriola K, Plantinga L, Gander JC, Hartmann E, Mulloy L, Zayas CF, Lee KN, Pastan SO, Patzer RE. **Association of sociocultural factors with initiation of the kidney**

transplant evaluation process. *Am J Transplant. 2020 Jan;20(1):190-203. doi: 10.1111/ajt.15526. Epub 2019 Aug 14.*

PMID: 31278832.

Abstract: Although research shows that minorities exhibit higher levels of medical mistrust, perceived racism, and discrimination in healthcare settings, the degree to which these underlying sociocultural factors preclude end-stage renal disease (ESRD) patients from initiating kidney transplant evaluation is unknown. We telephone surveyed 528 adult ESRD patients of black or white race referred for evaluation to a Georgia transplant center (N = 3) in 2014-2016. We used multivariable logistic regression to examine associations between sociocultural factors and evaluation initiation, adjusting for demographic, clinical, and socioeconomic characteristics. Despite blacks (n = 407) reporting higher levels of medical mistrust (40.0% vs 26.4%, P < .01), perceived racism (55.5% vs 18.2%, P < .01), and experienced discrimination (29.0% vs 15.7%, P < .01) than whites (n = 121), blacks were only slightly less likely than whites to initiate evaluation (49.6% vs 57.9%, P = .11). However, after adjustment, medical mistrust (odds ratio [OR]: 0.59; 95% confidence interval [CI]: 0.39, 0.91), experienced discrimination (OR: 0.62, 95% CI: 0.41, 0.95), and perceived racism (OR: 0.61; 95% CI: 0.40, 0.92) were associated with lower evaluation initiation. Results suggest that sociocultural disparities exist in early kidney transplant access and occur despite the absence of a significant racial disparity in evaluation initiation. Interventions to reduce disparities in transplantation access should target underlying sociocultural factors, not just race.

Keywords: disparities; end-stage renal disease; kidney transplant evaluation; race; sociocultural factors.

Hart A, Gustafson SK, Skeans MA, Stock P, Stewart D, Kasiske BL, Israni AK. **OPTN/SRTR 2015 Annual Data Report: Early effects of the new kidney allocation system.** *Am J Transplant. 2017 Jan;17 Suppl 1(Suppl 1):543-564. doi: 10.1111/ajt.14132.*

Notes: 2015 SRTR report, with particular interest being early results of the impact of the new kidney allocation system.

PMID: 28052605.

Abstract: In December 2014, a new kidney allocation system (KAS) was implemented in the United States in an attempt to improve access to transplant for historically underrepresented groups, and to incorporate longevity matching such that donor kidneys with the longest projected graft survival are given to recipients with the longest projected patient survival. The development of organ allocation policies is often guided by simulated allocation models, computer programs that simulate the arrival of donated organs and new candidates on the waiting list over a 1-year period to project outcomes under a new allocation method. We examined the early outcomes under the new KAS using quarterly data beginning in 2013, revealing whether trends were already underway before implementation. Quarterly data also serve to reveal any bolus effect, or a rapid rise or fall in the proportion of transplants in a given group due to reordering of the list, followed by tapering toward a new steady state. Post-KAS changes were notable for an increase in the proportion of transplants among younger candidates, black and Hispanic candidates, highly sensitized candidates, and those on dialysis for at least 5 years. Transplants among blood type B candidates increased slightly but these candidates remain underrepresented relative to their prevalence on the waiting list. Regional and national sharing increased under the new KAS, but transplants of kidneys with a kidney donor profile index above 85% decreased. Early graft survival appears unchanged, but given the increases in regional sharing, cold ischemia time, and transplants among highly sensitized candidates and candidates with long pretransplant dialysis time, long-term graft survival will need to monitored.

Hart A, Smith JM, Skeans MA, Gustafson SK, Wilk AR, Castro S, Robinson A, Wainright JL, Snyder JJ, Kasiske BL, Israni AK. **OPTN/SRTR 2017 Annual Data Report: Kidney.** *Am J Transplant. 2019 Feb;19 Suppl 2:19-123. doi: 10.1111/ajt.15274.*

Notes: 2017 SRTR report.

PMID: 30811893.

Abstract: Many positive trends in kidney transplantation were notable in 2017. Deceased donor kidney transplant rates and counts continued to rise, the kidney transplant waiting list declined for the third year in a row after decades of growth, and both short- and long-term allograft survival continued to improve year over year. In total, more than 220,000 patients were living in the United States with a functioning allograft. With 3 years of data available since implementation of the new kidney allocation system, better prediction of longer-term results of the allocation policy changes became possible. The data also reveal several areas in need of improvement and attention. Overall, the challenge of providing adequate access to kidney transplant persisted nationally, with additional dramatic regional variation. The proportion of living donor kidney transplants in both adults and children continued to fall, and racial disparities in living donor kidney transplant grew in the past decade.

Haugen CE, Chu NM, Ying H, Warsame F, Holscher CM, Desai NM, Jones MR, Norman SP, Brennan DC, Garonzik-Wang J, Walston JD, Bingaman AW, Segev DL, McAdams-DeMarco M. **Frailty and Access to Kidney Transplantation.** *Clin J Am Soc Nephrol. 2019 Apr 5;14(4):576-582. doi: 10.2215/CJN.12921118. Epub 2019 Mar 19.*

PMID: 30890577.

Abstract: Background and objectives: Frailty, a syndrome distinct from comorbidity and disability, is clinically manifested as a decreased resistance to stressors and is present in up to 35% of patient with ESKD. It is associated with falls, hospitalizations, poor cognitive function, and mortality. Also, frailty is associated with poor outcomes after kidney transplant, including delirium and mortality. Frailty is likely also associated with decreased access to kidney transplantation, given its association with poor outcomes on dialysis and post-transplant. Yet, clinicians have difficulty identifying which patients are frail; therefore, we sought to quantify if frail kidney transplant candidates had similar access to kidney transplantation as nonfrail candidates.

Design, setting, participants, & measurements: We studied 7078 kidney transplant candidates (2009-2018) in a three-center prospective cohort study of frailty. Fried frailty (unintentional weight loss, grip strength, walking speed, exhaustion, and activity level) was measured at outpatient kidney transplant evaluation. We estimated time to listing and transplant rate by frailty status using Cox proportional hazards and Poisson regression, adjusting for demographic and health factors.

Results: The mean age was 54 years (SD 13; range, 18-89), 40% were women, 34% were black, and 21% were frail. Frail participants were almost half as likely to be listed for kidney transplantation (hazard ratio, 0.62; 95% confidence interval, 0.56 to 0.69; P<0.001) compared with nonfrail participants, independent of age and other demographic factors. Furthermore, frail candidates were transplanted 32% less frequently than nonfrail candidates (incidence rate ratio, 0.68; 95% confidence interval, 0.58 to 0.81; P<0.001).

Conclusions: Frailty is associated with lower chance of listing and lower rate of transplant, and is a potentially modifiable risk factor.

Jones D, You Z, Kendrick JB. **Racial/Ethnic Differences in Barriers to Kidney Transplant Evaluation among Hemodialysis Patients.** *Am J Nephrol. 2018;47(1):1-7. doi: 10.1159/000484484. Epub 2017 Dec 19.*

PMID: 29258094.

Abstract: Background: Only a small percentage of dialysis patients receive a transplant and this is particularly the case for racial/ethnic minorities. Our objective was to identify barriers to initial transplant evaluation in our dialysis centers.

Methods: We conducted a survey of adult hemodialysis patients from 4 dialysis units in the Denver Metro area in 2016. Participants completed an 11-item survey with demographic information and questions regarding time on dialysis, if a provider ever spoke to them about transplant, and whether they had been evaluated for a transplant. Reasons for not having an evaluation were explored. Descriptive statistics, chi-square analyses, and multivariate analyses were used to examine the responses.

Results: A total of 167 patients completed the survey (response rate 63.9%). The majority of participants were male and were Hispanic (49%) or Non-Hispanic black (31.7%). Of these, 140 patients (84.0%) reported discussing kidney transplantation with their doctor but only 53% reported having a transplant evaluation. After adjustment for age, gender, and time on dialysis, significantly fewer blacks reported having an evaluation than Non-Hispanic whites or Hispanics

(43.4 vs. 57.7% [whites] and 59.7% [Hispanics], p = 0.03). The most frequent responses of the patients who had not been evaluated were the following: not referred by their provider (46%), did not know how to proceed (43.4%), or did not understand the benefits (39.5%) or transplant process (38.2%). Compared to Non-Hispanic whites, blacks and Hispanics reported less understanding of the benefits and process of transplant.

Conclusion: Timely referral by providers and improved kidney transplantation education may reduce disparities in access to kidney transplantation.

Keddis MT, Sharma A, Ilyas M, Zhang N, Khamash H, Leischow SJ, Heilman RL. **Transplant center assessment of the inequity in the kidney transplant process and outcomes for the Indigenous American patients.** *PLoS One. 2018 Nov 21;13(11):e0207819. doi: 10.1371/journal.pone.0207819. eCollection 2018.*

PMID: 30462724.

Abstract: Background: The goal is to determine the delays and reduced rates of kidney transplant (KTx) for the Indigenous Americans and variables predictive of these outcomes at a large single transplant center.

Methods: 300 Indigenous Americans and 300 non-Hispanic white American patients presenting for KTx evaluation from 2012-2016 were studied.

Results: Compared to whites, the Indigenous Americans had the following: more diabetes, dialysis, physical limitation and worse socioeconomic characteristics(p<0.01); median difference of 20 day delay from referral to KTx evaluation, 17 day delay from approval to UNOS listing and 126.5 longer delay on the waitlist compared to whites(p<0.001). Of the Indigenous Americans listed, more died, were removed, or were still waiting than transplanted compared to whites (p<0.001). Variables predictive of delay from referral to transplant evaluation included: Indigenous race, distance from transplant center, coronary artery disease, and time on dialysis (p<0.05). Cumulative incidence of waitlisting and KTx was lower for Indigenous Americans (p<0.0001). Independent predictors of decreased likelihood of waitlisting included age, peripheral vascular disease, no caregiver, physical limitation, and illegal drug use history (p<0.05). Variables predictive of lower likelihood of KTx included Indigenous race, percentage of time inactive on the waitlist, no caregiver, and O blood type.

Conclusions: Among patients referred and evaluated for KTx, the Indigenous American race was independently associated with significant delays in the KTx process after accounting for co-morbid and socioeconomic factors. Cardiovascular morbidity and physical limitation were identified as important determinants of delay and decreased likelihood of waitlisting. Further quantitative and qualitative work is needed to identify and intervene on modifiable barriers to improve access to KTx for the Indigenous Americans.

Kim JJ, Basu M, Plantinga L, Pastan SO, Mohan S, Smith K, Melanson T, Escoffery C, Patzer RE. **Awareness of Racial Disparities in Kidney Transplantation among Health Care Providers in Dialysis Facilities.** *Clin J Am Soc Nephrol. 2018 May 7;13(5):772-781. doi: 10.2215/CJN.09920917. Epub 2018 Apr 12.*

PMID: 29650714.

Abstract: Background and objectives: Despite the important role that health care providers at dialysis facilities have in reducing racial disparities in access to kidney transplantation in the United States, little is known about provider awareness of these disparities. We aimed to evaluate health care providers' awareness of racial disparities in kidney transplant waitlisting and identify factors associated with awareness.

Design, setting, participants, & measurements: We conducted a cross-sectional analysis of a survey of providers from low-waitlisting dialysis facilities (n=655) across all 18 ESRD networks administered in 2016 in the United States merged with 2014 US Renal Data System and 2014 US Census data. Awareness of national racial disparity in waitlisting was defined as responding "yes" to the question: "Nationally, do you think that African Americans currently have lower waitlisting rates than white patients on average?" The secondary outcome was providers' perceptions of racial difference in waitlisting at their own facilities.

Results: Among 655 providers surveyed, 19% were aware of the national racial disparity in waitlisting: 50% (57 of 113) of medical directors, 11% (35 of 327) of nurse managers, and 16% (35 of 215) of other providers. In analyses adjusted for provider and facility characteristics, nurse managers (versus medical directors; odds ratio, 7.33; 95% confidence interval, 3.35 to 16.0) and white providers (versus black providers; odds ratio, 2.64; 95% confidence interval, 1.39 to 5.02) were more likely to be unaware of a national racial disparity in waitlisting. Facilities in the South (versus the Northeast; odds ratio, 3.05; 95% confidence interval, 1.04 to 8.94) and facilities with a low percentage of blacks (versus a high percentage of blacks; odds ratio, 1.86; 95% confidence interval, 1.02 to 3.39) were more likely to be unaware. One quarter of facilities had >5% racial difference in waitlisting within their own facilities, but only 5% were aware of the disparity.

Conclusions: Among a limited sample of dialysis facilities with low waitlisting, provider awareness of racial disparities in kidney transplant waitlisting was low, particularly among staff who may have more routine contact with patients.

King KL, Husain SA, Jin Z, Brennan C, Mohan S. **Trends in Disparities in Preemptive Kidney Transplantation in the United States.** *Clin J Am Soc Nephrol. 2019 Oct 7;14(10):1500-1511. doi: 10.2215/CJN.03140319. Epub 2019 Sep 26.*

PMID: 31413065.

Abstract: Background and objectives: Long wait times for deceased donor kidneys and low rates of preemptive wait-listing have limited preemptive transplantation in the United States. We aimed to assess trends in preemptive deceased donor transplantation with the introduction of the new Kidney Allocation System (KAS) in 2014 and identify whether key disparities in preemptive transplantation have changed.

Design, setting, participants, & measurements: We identified adult deceased donor kidney transplant recipients in the United States from 2000 to 2018 using the Scientific Registry of Transplant Recipients. Preemptive transplantation was defined as no dialysis before transplant. Associations between recipient, donor, transplant, and policy era characteristics and preemptive transplantation were calculated using logistic regression. To test for modification by KAS policy era, an interaction term between policy era and each characteristic of interest was introduced in bivariate and adjusted models.

Results: The proportion of preemptive transplants increased after implementation of KAS from 9.0% to 9.8%, with 1.10 (95% confidence interval [95% CI], 1.06 to 1.14) times higher odds of preemptive transplantation post-KAS compared with pre-KAS. Preemptive recipients were more likely to be white, older, female, more educated, hold private insurance, and have ESKD cause other than diabetes or hypertension. Policy era significantly modified the association between preemptive transplantation and race, age, insurance status, and Human Leukocyte Antigen zero-mismatch (interaction P<0.05). Medicare patients had a significantly lower odds of preemptive transplantation relative to private insurance holders (pre-KAS adjusted OR, [aOR] 0.26; [95% CI, 0.25 to 0.27], to 0.20 [95% CI, 0.18 to 0.22] post-KAS). Black and Hispanic patients experienced a similar phenomenon (aOR 0.48 [95% CI, 0.45 to 0.51] to 0.41 [95% CI, 0.37 to 0.45] and 0.43 [95% CI, 0.40 to 0.47] to 0.40 [95% CI, 0.36 to 0.46] respectively) compared with white patients.

Conclusions: Although the proportion of deceased donor kidney transplants performed preemptively increased slightly after KAS, disparities in preemptive kidney transplantation persisted after the 2014 KAS policy changes and were exacerbated for racial minorities and Medicare patients.

Keywords: European Continental Ancestry Group; HLA antigens; Hispanic Americans; Insurance Coverage; Medicare; Registries; United States; adult; allocation system; chronic kidney failure; deceased donor; diabetes mellitus; female; health policy; humans; hypertension; kidney failure, chronic; kidney transplantation; logistic models; preemptive kidney transplantation; renal dialysis; tissue donors; transplant recipients; unintended consequences.

Ku E, Lee BK, McCulloch CE, Roll GR, Grimes B, Adey D, Johansen KL. **Racial and Ethnic Disparities in Kidney Transplant Access Within a Theoretical Context of Medical Eligibility.** *Transplantation. 2020 Jul;104(7):1437-1444. doi: 10.1097/TP.0000000000002962.*

Notes: Large dialysis registry based analyses showing persistent disparities in access to transplantation even in healthy cohorts.

PMID: 31568216.

Abstract: Background: Non-Hispanic black (NHB) and Hispanic patients have lower access to kidney transplantation compared to non-Hispanic whites (NHWs). We examined whether differences in the prevalence of comorbidities that affect eligibility for transplant contribute to disparities in receipt of transplantation.

Methods: We performed a retrospective study of 986 019 adults who started dialysis between 2005 and 2014, according to the United States Renal Data System. We compared prevalence of comorbidities that could influence transplant eligibility by race/ethnicity. We examined time to first transplant by race/ethnicity in this overall cohort and in a very healthy sub-cohort without conditions that could be contraindications to transplantation.

Results: During 2.3 years of mean follow-up, 64 892 transplants occurred. NHBs and Hispanics had a lower prevalence of medical barriers to transplantation at the time of dialysis initiation than NHWs, including age >70 years (26% in NHB versus 47% in NHW) and malignancy (4% in Hispanics versus 10% in NHWs). Access to transplant was 65% lower (95% CI, 0.33-0.37) in NHBs and 43% lower (95% CI, 0.54-0.62) in Hispanics (versus NHWs) in the first year after end-stage renal disease, but by Year 4, access to transplantation was not statistically significantly different between Hispanics or NHBs (versus NHWs). In our very healthy cohort, racial and ethnic disparities in access to transplantation persisted up to Year 5 in NHBs and Year 4 in Hispanics after end-stage renal disease onset.

Conclusions: Differences in medical eligibility do not appear to explain racial/ethnic disparities in receipt of kidney transplantation and may mask the actual magnitude of the inequities that are present.

Ku E, Whelan AM, McCulloch CE, Lee B, Niemann CU, Roll GR, Grimes BA, Johansen KL. **Weighing the waitlist: Weight changes and access to kidney transplantation among obese candidates.** *PLoS One. 2020 Nov 30;15(11):e0242784. doi: 10.1371/journal.pone.0242784. eCollection 2020.*

PMID: 33253253.

Abstract: High body mass index is a known barrier to access to kidney transplantation in patients with end-stage kidney disease. The extent to which weight and weight changes affect access to transplantation among obese candidates differentially by race/ethnicity has received little attention. We included 10 221 obese patients waitlisted for kidney transplantation prior to end-stage kidney disease onset between 1995-2015. We used multinomial logistic regression models to examine the association between race/ethnicity and annualized change in body mass index (defined as stable [-2 to 2 kg/m2/year], loss [>2 kg/m2/year] or gain [>2 kg/m2/year]). We then used Fine-Gray models to examine the association between weight changes and access to living or deceased donor transplantation by race/ethnicity, accounting for the competing risk of death. Overall, 29% of the cohort lost weight and 7% gained weight; 46% received a transplant. Non-Hispanic blacks had a 24% (95% CI 1.12-1.38) higher odds of weight loss and 22% lower odds of weight gain (95% CI 0.64-0.95) compared with non-Hispanic whites. Hispanics did not differ from whites in their odds of weight loss or weight gain. Overall, weight gain was associated with lower access to transplantation (HR 0.88 [95% CI 0.79-0.99]) compared with maintenance of stable weight, but weight loss was not associated with better access to transplantation (HR 0.96 [95% CI 0.90-1.02]), although this relation differed by baseline body mass index and for recipients of living versus deceased donor organs. For example, weight loss was associated with improved access to living donor transplantation (HR 1.24 [95% CI 1.07-1.44]) in whites but not in blacks or Hispanics. In a cohort of obese patients waitlisted before dialysis, blacks were more likely to lose weight and less likely to gain weight compared with whites. Weight loss was only associated with improved access to living donor transplantation among whites. Further studies are needed to understand the reasons for the observed associations.

Kucirka, L M & Grams, M E & Balhara, K S & Jaar, B G & Segev, D L **Disparities in provision of transplant information affect access to kidney transplantation.** *Am J Transplant. 2012 Feb;12(2):351-7. doi: 10.1111/j.1600-6143.2011.03865.x. Epub 2011 Dec 7.*

Notes: US national observational study of incident ESRD patients using 2728 Form reported data re. whether or not patient was informed of transplant options at time of start of dialysis.

PMID: 22151011.

Abstract: Recently Centers for Medicare and Medicaid Services (CMS) began asking providers on Form-2728 whether they informed patients about transplantation, and if not, to select a reason. The goals of this study were to describe national transplant education practices and analyze associations between practices and access to transplantation (ATT), based on United States Renal Data System (USRDS) data from 2005 to 2007. Multinomial logistic regression was used to examine factors associated with not being informed about transplantation, and modified Poisson regression to examine associations between not being informed and ATT (all models adjusted for demographics/comorbidities). Of 236,079 incident end-stage renal disease (ESRD) patients, 30.1% were not informed at time of 2728 filing, for reasons reported by providers as follows: 42.1% unassessed, 30.4% medically unfit, 16.9% unsuitable due to age, 3.1% psychologically unfit and 1.5% declined counsel. Older, obese, uninsured, Medicaid-insured and patients at for-profit centers were more likely to be unassessed. Women were more likely to be reported as unsuitable due to age, medically unfit and declined, and African Americans as psychologically unfit. Uninformed patients had a 53% lower rate of ATT, a disparity persisting in the subgroup of uninformed patients who were unassessed. Disparities in ATT may be partially explained by disparities in provision of transplant information; dialysis centers should ensure this critical intervention is offered equitably.

Kulkarni S, Ladin K, Haakinson D, Greene E, Li L, Deng Y. **Association of Racial Disparities With Access to Kidney Transplant After the Implementation of the New Kidney Allocation System.** *JAMA Surg. 2019 Jul 1;154(7):618-625. doi: 10.1001/jamasurg.2019.0512.*

Notes: Examines the importance of transitions from inactive to active status on the waitlist to disparities in access to transplantation.

PMID: 30942882.

Abstract: Importance: Inactive patients on the kidney transplant wait-list have a higher mortality. The implications of this status change on transplant outcomes between racial/ethnic groups are unknown.

Objectives: To determine if activity status changes differ among races/ethnicities and levels of sensitization, and if these differences are associated with transplant probability after implementation of the Kidney Allocation System.

Design, setting, and participants: A multistate model was constructed from the Organ Procurement and Transplantation Network kidney transplant database (December 4, 2014, to September 8, 2016). The time interval followed Kidney Allocation System implementation and provided at least 1-year follow-up for all patients. The model calculated probabilities between active and inactive status and the following competing risk outcomes: living donor transplant, deceased donor transplant, and death/other. This retrospective cohort study included 42 558 patients on the Organ Procurement and Transplantation Network kidney transplant wait-list following Kidney Allocation System implementation. To rule out time-varying confounding from relisting, analysis was limited to first-time registrants. Owing to variations in listing practices, primary center listing data were used for dually listed patients. Individuals listed for another organ or pancreatic islets were excluded. Analysis began July 2017.

Main outcome and measures: Probabilities were determined for transitions between active and inactive status and the following outcome states: active to living donor transplant, active to deceased donor transplant, active to death/other, inactive to living donor transplant, inactive to deceased donor transplant, and inactive to death/other.

Results: The median (interquartile range) age at listing was 55.0 (18.0-89.0) years, and 26 535 of 42 558 (62.4%) were men. White individuals were 43.3% (n = 18 417) of wait-listed patients, while black and Hispanic individuals made up 27.8% (n = 11 837) and 19.5% (n = 8296), respectively. Patients in the calculated plasma reactive antibody categories of 0% or 1% to 79% showed no statistically significant difference in transplant probability among races/ethnicities. White individuals had an advantage in transplant probability over black individuals in calculated plasma reactive antibody categories of 80% to 89% (hazard ratio [HR], 1.8 [95% CI, 1.4-2.2]) and 90% or higher (HR, 2.4 [95% CI, 2.1-2.6]), while Hispanic individuals had an advantage over black individuals in the calculated plasma reactive antibody group of 90% or higher (HR, 2.5 [95% CI, 2.1-2.8]). Once on the inactive list, white individuals were more likely than Hispanic individuals (HR, 1.2 [95% CI, 1.17-1.3]) or black individuals (HR, 1.4 [95% CI, 1.3-1.4]) to resolve issues for inactivity resulting in activation.

Conclusions and relevance: For patients who are highly sensitized, there continues to be less access to kidney transplant in the black population after the implementation of the Kidney Allocation System. Health disparities continue after listing where individuals from minority groups have greater difficulty in resolving issues of inactivity.

Ladin K, Emerson J, Berry K, Butt Z, Gordon EJ, Daniels N, Lavelle TA, Hanto DW. **Excluding patients from transplant due to social support: Results from a national survey of transplant providers.** *Am J Transplant. 2019 Jan;19(1):193-203. doi: 10.1111/ajt.14962. Epub 2018 Jul 2.*

Notes: Large multicenter survey of transplant providers examining perceived importance of social support to transplant eligibility.

PMID: 29878515.

Abstract: Social support is used to determine transplant eligibility despite lack of an evidence base and vague regulatory guidance. It is unknown how many patients are disqualified from transplantation due to inadequate support, and whether providers feel confident using these subjective criteria to determine eligibility. Transplant providers (n = 551) from 202 centers estimated that, on average, 9.6% (standard deviation = 9.4) of patients evaluated in the prior year were excluded due to inadequate support. This varied significantly by United Network for Organ Sharing region (7.6%-12.2%), and by center (21.7% among top quartile). Significantly more providers used social support in listing decisions than believed it ought to be used (86.3% vs 67.6%). Nearly 25% believed that using social support in listing determinations was unfair or were unsure; 67.3% felt it disproportionately impacted patients of low socioeconomic status. Overall, 42.4% were only somewhat or not at all confident using social support to determine transplant suitability. Compared to surgical/medical transplant providers, psychosocial providers had 2.13 greater odds of supporting the criteria (P = .03). Furthermore, 69.2% supported revised guidelines for use of social support in listing decisions. Social support criteria should be reconsidered in light of the limited evidence, potential for disparities, practice variation, low provider confidence, and desire for revised guidelines.

Ladin, K & Rodrigue, J R & Hanto, D W **Framing disparities along the continuum of care from chronic kidney disease to transplantation: barriers and interventions.** *Am J Transplant. 2009 Apr;9(4):669-74. doi: 10.1111/j.1600-6143.2009.02561.x.*

Notes: Disparities review and contextual framework as general background information.

PMID: 19344460.

Abstract: Research in renal transplantation continues to document scores of disparities affecting vulnerable populations at various stages along the transplantation process. Given that both biological and environmental determinants contribute significantly to variation, identifying factors underlying an unfairly biased distribution of the disease burden is crucial. Confounded definitions and gaps in understanding causal pathways impede effectiveness of interventions aimed at alleviating disparities. This article offers an operational definition of disparities in the context of a framework aimed at facilitating interventional research. Utilizing an original framework describing the entire continuum of the transplant process from diagnosis of chronic kidney disease through successful transplant, this article explores the case of racial disparities, illustrating key factors predicting and perpetuating disparities. Though gaps in current research leave us unable to identify which stages of the transplant pathway adversely affect most people, by identifying key risk factors across the continuum of care, this article highlights areas suited for targeted interventions and presents recommendations for improvement and future research.

Locke JE, Mehta S, Sawinski D, Gustafson S, Shelton BA, Reed RD, MacLennan P, Bolch C, Durand C, Massie A, Mannon RB, Gaston R, Saag M, Overton T, Segev DL. **Access to Kidney Transplantation among HIV-Infected Waitlist Candidates.** *Clin J Am Soc Nephrol. 2017 Mar 7;12(3):467-475. doi: 10.2215/CJN.07460716. Epub 2017 Feb 23.*

PMID: 28232406.

Abstract: Background and objectives: Kidney transplantation among HIV-infected patients with ESRD confers a significant survival benefit over remaining on dialysis. Given the high mortality burden associated with dialysis, understanding access to kidney transplantation after waitlisting among HIV+ candidates is warranted.

Design, setting, participants, & measurements: Data from the Scientific Registry of Transplant Recipients were linked to Intercontinental Marketing Statistics pharmacy fills (January 1, 2001 to October 1, 2012) so that we could identify and study 1636 HIV+ (defined as having filled one or more antiretroviral medications unique to HIV treatment) and 72,297 HIV- kidney transplantation candidates.

Results: HIV+ waiting list candidates were more often young (<50 years old: 62.7% versus 37.6%; P<0.001), were more often men (75.2% versus 59.3%; P<0.001), were more often black (73.6% versus 27.9%; P<0.001), had longer time on dialysis (years: 2.5 versus 0.8; P<0.001), were more often coinfected with hepatitis C virus (9.0% versus 3.9%; P<0.001), and were less likely to remain active on the waiting list (37.7% versus 49.4%; P<0.001). Waitlist mortality among HIV+ candidates was similar compared with HIV- candidates (adjusted hazard ratio, 1.03; 95% confidence interval, 0.89 to 1.20; P=0.67). In contrast, likelihood of living donor kidney transplantation was 47% lower (adjusted hazard ratio, 0.53; 95% confidence interval, 0.44 to 0.64; P<0.001), and there was a trend toward lower likelihood of deceased donor kidney transplantation (adjusted hazard ratio, 0.87; 95% confidence interval, 0.74 to 1.01; P=0.07) compared with in HIV- candidates.

Conclusions: Our findings highlight the need for additional study to better understand disparities in access to kidney transplantation, particularly living donor kidney transplantation, among HIV+ kidney waitlist candidates.

Locke JE, Reed RD, Kumar V, Berry B, Hendricks D, Carter A, Shelton BA, Mustian MN, MacLennan PA, Qu H, Hannon L, Yates C, Hanaway MJ. **Enhanced Advocacy and Health Systems Training Through Patient Navigation Increases Access to Living-donor Kidney Transplantation.** *Transplantation. 2020 Jan;104(1):122-129. doi: 10.1097/TP.0000000000002732.*

PMID: 30946213.

Abstract: Background: To date, no living donation program has simultaneously addressed the needs of both transplant candidates and living donors by separating the advocacy role from the candidate and improving potential donor comfort with the evaluation process. We hypothesized that the development of a novel program designed to promote both advocacy and systems training among transplant candidates and their potential living kidney donors would result in sustained increases in living-donor kidney transplantation (LDKT). To this end, we developed and implemented a Living Donor Navigator (LDN) Program at the University of Alabama at Birmingham.

Methods: We included adult patients awaiting kidney-only transplant in a retrospective cohort analysis. Using time-varying Cox proportional hazards regression, we explored likelihood of living donor screening and approval by participation in the LDN program.

Results: There were 56 LDN participants and 1948 nonparticipants (standard of care). LDN was associated with a 9-fold increased likelihood of living donor screenings (adjusted hazard ratio, 9.27; 95% confidence interval, 5.97-14.41, P < 0.001) and a 7-fold increased likelihood of having an approved living donor (adjusted hazard ratio, 7.74; 95% confidence interval, 3.54-16.93; P < 0.001) compared with the standard of care. Analyses by participant race demonstrated higher likelihood of screened donors and a similar likelihood of having an approved donor among African Americans compared with Caucasians.

Conclusions: These data suggest that both advocacy and systems training are needed to increase actual LDKT rates, and that LDN programs may mitigate existing racial disparities in access to LDKT.

Mandelbrot DA, Fleishman A, Rodrigue JR, Norman SP, Samaniego M. **Practices in the evaluation of potential kidney transplant recipients who are elderly: A survey of U.S. transplant centers.** *Clin Transplant. 2017 Oct;31(10). doi: 10.1111/ctr.13088. Epub 2017 Sep 4.*

PMID: 28805267.

Abstract: Limited data exist regarding the evaluation and selection of older candidates for transplantation. To help guide the development of program protocols and help define research questions in this area, we surveyed U.S. transplant centers regarding their current practices in the evaluation of older kidney transplant candidates. We emailed a 28-question survey to the medical and surgical directors of 190 adult kidney transplant programs in the USA. We received usable responses from 59 programs, a 31.1% response rate. Most (76.3%) programs do not have absolute age cutoffs for listing patients, but for the 22.0% of programs that do have cutoffs, the mean age was 79, range 70-90. Nearly one-third (29.2%) of programs require a minimum life expectancy to list for transplant, reporting a mean of 4.5 years life expectancy, (range 2-10). Programs vary significantly in evaluating candidates living in a nursing home or with cognitive impairments. Practices regarding the evaluation of older transplant candidates vary widely between U.S. programs. Further studies are needed on the impact of age and other comorbidities on transplant outcomes, to help guide decisions on which older patients are most appropriate for transplant listing.

Massie AB, Luo X, Lonze BE, Desai NM, Bingaman AW, Cooper M, Segev DL. **Early Changes in Kidney Distribution under the New Allocation System.** *J Am Soc Nephrol. 2016 Aug;27(8):2495-501. doi: 10.1681/ASN.2015080934. Epub 2015 Dec 17.*

PMID: 26677865.

Abstract: The Kidney Allocation System (KAS), a major change to deceased donor kidney allocation, was implemented in December 2014. Goals of KAS included directing the highest-quality organs to younger/healthier recipients and increasing access to deceased donor kidney transplantation (DDKT) for highly sensitized patients and racial/ethnic minorities. Using national registry data, we compared kidney distribution, DDKT rates for waitlist registrants, and recipient characteristics between January 1, 2013, and December 3, 2014 (pre-KAS) with those between December 4, 2014, and August 31, 2015 (post-KAS). Regional imports increased from 8.8% pre-KAS to 12.5% post-KAS; national imports increased from 12.7% pre-KAS to 19.1% post-KAS (P<0.001). The proportion of recipients >30 years older than their donor decreased from 19.4% to 15.0% (P<0.001). The proportion of recipients with calculated panel-reactive antibody =100 increased from 1.0% to 10.3% (P<0.001). Overall DDKT rate did not change as modeled using exponential regression adjusting for candidate characteristics (P=0.07). However, DDKT rate (incidence rate ratio, 95% confidence interval) increased for black (1.19; 1.13 to 1.25) and Hispanic (1.13; 1.05 to 1.20) candidates and for candidates aged 18-40 (1.47; 1.38 to 1.57), but declined for candidates aged >50 (0.93; 0.87 to 0.98 for aged 51-60 and 0.90; 0.85 to 0.96 for aged >70). Delayed graft function in transplant recipients increased from 24.8% pre-KAS to 29.9% post-KAS (P<0.001). Thus, in the first 9 months under KAS, access to DDKT improved for minorities, younger candidates, and highly sensitized patients, but declined for older candidates. Delayed graft function increased substantially, possibly suggesting poorer long-term outcomes.

Myaskovsky L, Kendall K, Li X, Chang CH, Pleis JR, Croswell E, Ford CG, Switzer GE, Langone A, Mittal-Henkle A, Saha S, Thomas CP, Adams Flohr J, Ramkumar M, Dew MA. **Unexpected Race and Ethnicity Differences in the US National Veterans Affairs Kidney Transplant Program.** *Transplantation. 2019 Dec;103(12):2701-2714. doi: 10.1097/TP.0000000000002905.*

PMID: 31397801.

Abstract: Background: Racial/ethnic minorities have lower rates of deceased kidney transplantation (DDKT) and living donor kidney transplantation (LDKT) in the United States. We examined whether social determinants of health (eg, demographics, cultural, psychosocial, knowledge factors) could account for differences in the Veterans Affairs (VA) Kidney Transplantation (KT) Program.

Methods: We conducted a multicenter longitudinal cohort study of 611 Veterans undergoing evaluation for KT at all National VA KT Centers (2010-2012) using an interview after KT evaluation and tracking participants via medical records through 2017.

Results: Hispanics were more likely to get any KT (subdistribution hazard ratios [SHR] [95% confidence interval (CI)]: 1.8 [1.2-2.8]) or DDKT (SHR [95% CI]: 2.0 [1.3-3.2]) than non-Hispanic white in univariable analysis. Social determinants of health, including marital status (SHR [95% CI]: 0.6 [0.4-0.9]), religious objection to LDKT (SHR [95% CI]: 0.6 [0.4-1.0]), and donor preference (SHR [95% CI]: 2.5 [1.2-5.1]), accounted for some racial differences, and changes to Kidney Allocation System policy (SHR [95% CI]: 0.3 [0.2-0.5]) mitigated race differences in DDKT in multivariable analysis. For LDKT, non-Hispanic African American Veterans were less likely to receive an LDKT than non-Hispanic white (SHR [95% CI]: 0.2 [0.0-0.7]), but accounting for age (SHR [95% CI]: 1.0 [0.9-1.0]), insurance (SHR [95% CI]: 5.9 [1.1-33.7]), presenting with a living donor (SHR [95% CI]: 4.1 [1.4-12.3]), dialysis duration (SHR [95% CI]: 0.3 [0.2-0.6]), network of potential donors (SHR [95% CI]: 1.0 [1.0-1.1]), self-esteem (SHR [95% CI]: 0.4 [0.2-0.8]), transplant knowledge (SHR [95% CI]: 1.3 [1.0-1.7]), and changes to Kidney Allocation System policy (SHR [95% CI]: 10.3 [2.5-42.1]) in multivariable analysis eliminated those disparities.

Conclusions: The VA KT Program does not exhibit the same pattern of disparities in KT receipt as non-VA centers. Transplant centers can use identified risk factors to target patients who may need more support to ensure they receive a transplant.

Newman KL, Fedewa SA, Jacobson MH, Adams AB, Zhang R, Pastan SO, Patzer RE. **Racial/Ethnic Differences in the Association Between Hospitalization and Kidney Transplantation Among Waitlisted End-Stage Renal Disease Patients.** *Transplantation. 2016 Dec;100(12):2735-2745. doi: 10.1097/TP.0000000000001072.*

PMID: 26845307.

Abstract: Background: Even after placement on the deceased donor waitlist, there are racial disparities in access to kidney transplant. The association between hospitalization, a proxy for health while waitlisted, and disparities in kidney transplant has not been investigated.

Methods: We used United States Renal Data System Medicare-linked data on waitlisted end-stage renal disease patients between 2005 and 2009 with continuous enrollment in Medicare Parts A & B (n = 24 581) to examine the association between annual hospitalization rate and odds of receiving a deceased donor kidney transplant. We used multilevel mixed effects models to estimate adjusted odds ratios, controlling for individual-, transplant center-, and organ procurement organization-level clustering.

Results: Blacks and Hispanics were more likely than whites to be hospitalized for circulatory system or endocrine, nutritional, and metabolic diseases ($P < 0.001$). After adjustment, compared with individuals not hospitalized, patients who were hospitalized frequently while waitlisted were less likely to be transplanted (>2 vs 0 hospitalizations/year adjusted odds ratios

= 0.57; P < 0.001). Though blacks and Hispanics were more likely to be hospitalized than whites (P < 0.001), adjusting for hospitalization did not change estimated racial/ethnic disparities in kidney transplantation.

Conclusions: Individuals hospitalized while waitlisted were less likely to receive a transplant. However, hospitalization does not account for the racial disparity in kidney transplantation after waitlisting.

Ng YH, Pankratz VS, Leyva Y, Ford CG, Pleis JR, Kendall K, Croswell E, Dew MA, Shapiro R, Switzer GE, Unruh ML, Myaskovsky L. **Does Racial Disparity in Kidney Transplant Waitlisting Persist After Accounting for Social Determinants of Health?.** *Transplantation. 2020 Jul;104(7):1445-1455. doi: 10.1097/TP.0000000000003002.*

PMID: 31651719.

Abstract: Background: African Americans (AA) have lower rates of kidney transplantation (KT) compared with Whites (WH), even after adjusting for demographic and medical factors. In this study, we examined whether the racial disparity in KT waitlisting persists after adjusting for social determinants of health (eg, cultural, psychosocial, and knowledge).

Methods: We prospectively followed a cohort of 1055 patients who were evaluated for KT between 3 of 10 to 10 of 12 and followed through 8 of 18. Participants completed a semistructured telephone interview shortly after their first KT evaluation appointment. We used the Wilcoxon rank-sum and Pearson chi-square tests to examine race differences in the baseline characteristics. We then assessed racial differences in the probability of waitlisting while accounting for all predictors using cumulative incidence curves and Fine and Gray proportional subdistribution hazards models.

Results: There were significant differences in the baseline characteristics between non-Hispanic AA and non-Hispanic WH. AA were 25% less likely (95% confidence interval, 0.60-0.96) to be waitlisted than WH even after adjusting for medical factors and social determinants of health. In addition, being older, having lower income, public insurance, more comorbidities, and being on dialysis decreased the probability of waitlisting while having more social support and transplant knowledge increased the probability of waitlisting.

Conclusions: Racial disparity in kidney transplant waitlisting persisted even after adjusting for medical factors and social determinants of health, suggesting the need to identify novel factors that impact racial disparity in transplant waitlisting. Developing interventions targeting cultural and psychosocial factors may enhance equity in access to transplantation.

Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. **Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program.** *2020. https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-purchasing-programs*

Abstract: As required by the IMPACT Act, the second Report to Congress examines the effect of individuals' social risk factors on quality measures, resource use, and other measures under the Medicare program, as well as analyses of the effects of Medicare's current value-based payment programs on providers serving socially at-risk beneficiaries and simulations of potential policy options to address these issues. This Report also examined how HHS can achieve better outcomes for all Medicare beneficiaries by facilitating the ability of providers and communities to address social risk factors and integrate health and social services. Empirical analyses for this Report used existing Medicare data and additional, non-Medicare data sources.

Patzer RE, Basu M, Larsen CP, Pastan SO, Mohan S, Patzer M, Konomos M, McClellan WM, Lea J, Howard D, Gander J, Arriola KJ. **iChoose Kidney: A Clinical Decision Aid for Kidney Transplantation Versus Dialysis Treatment.** *Transplantation. 2016 Mar;100(3):630-9. doi: 10.1097/TP.0000000000001019.*

PMID: 26714121.

Abstract: Background: Despite a significant survival advantage of kidney transplantation compared with dialysis, nearly one third of end-stage renal disease (ESRD) patients are not educated about kidney transplantation as a treatment option at the time of ESRD diagnosis. Access to individualized, evidence-based prognostic information is needed to facilitate and encourage shared decision making about the clinical implications of whether to pursue transplantation or long-term dialysis.

Methods: We used a national cohort of incident ESRD patients in the US Renal Data System surveillance registry from 2005 to 2011 to develop and validate prediction models for risk of 1- and 3-year mortality among dialysis versus kidney transplantation. Using these data, we developed a mobile clinical decision aid that provides estimates of risks of death and survival on dialysis compared with kidney transplantation patients.

Results: Factors included in the mortality risk prediction models for dialysis and transplantation included age, race/ethnicity, dialysis vintage, and comorbidities, including diabetes, hypertension, cardiovascular disease, and low albumin. Among the validation cohorts, the discriminatory ability of the model for 3-year mortality was moderate (c statistic, 0.7047; 95% confidence interval, 0.7029-0.7065 for dialysis and 0.7015; 95% confidence interval, 0.6875-0.7155 for transplant). We used these risk prediction models to develop an electronic, user-friendly, mobile (iPad, iPhone, and website) clinical decision aid called iChoose Kidney.

Conclusions: The use of a mobile clinical decision aid comparing individualized mortality risk estimates for dialysis versus transplantation could enhance communication between ESRD patients and their clinicians when making decisions about treatment options.

Patzer RE, McPherson L, Basu M, Mohan S, Wolf M, Chiles M, Russell A, Gander JC, Friedewald JJ, Ladner D, Larsen CP, Pearson T, Pastan S. **Effect of the iChoose Kidney decision aid in improving knowledge about treatment options among transplant candidates: A randomized controlled trial.** *Am J Transplant. 2018 Aug;18(8):1954-1965. doi: 10.1111/ajt.14693. Epub 2018 Mar 26.*

Notes: Randomized trial of decision aid on transplant knowledge for patients.

PMID: 29446209.

Abstract: We previously developed a mobile- and web-based decision aid (iChoose Kidney) that displays individualized risk estimates of survival and mortality, for the treatment modalities of dialysis versus kidney transplantation. We examined the effect of iChoose Kidney on change in transplant knowledge and access to transplant in a randomized controlled trial among patients presenting for evaluation in three transplant centers. A total of 470 patients were randomized to standard transplantation education (control) or standard education plus iChoose Kidney (intervention). Change in transplant knowledge (primary outcome) among intervention versus control patients was assessed using nine items in pre- and postevaluation surveys. Access to transplant (secondary outcome) was defined as a composite of waitlisting, living donor inquiries, or transplantation. Among 443 patients (n = 226 intervention; n = 216 control), the mean knowledge scores were 5.1 ± 2.1 pre- and 5.8 ± 1.9 postevaluation. Change in knowledge was greater among intervention (1.1 ± 2.0) versus control (0.4 ± 1.8) patients ($P < .0001$). Access to transplantation was similar among intervention (n = 168; 74.3%) versus control patients (n = 153; 70.5%; $P = .37$). The iChoose Kidney decision aid improved patient knowledge at evaluation, but did not impact transplant access. Future studies should examine whether combining iChoose Kidney with other interventions can increase transplantation. (Clinicaltrials.gov NCT02235571).

Patzer RE, Paul S, Plantinga L, Gander J, Sauls L, Krisher J, Mulloy LL, Gibney EM, Browne T, Zayas CF, McClellan WM, Arriola KJ, Pastan SO; Southeastern Kidney Transplant Coalition. **A Randomized Trial to Reduce Disparities in Referral for Transplant Evaluation.** *J Am Soc Nephrol. 2017 Mar;28(3):935-942. doi: 10.1681/ASN.2016030320. Epub 2016 Oct 13.*

Notes: Randomized trial of multicomponent intervention (RaDIANT study) directed at dialysis facilities to increase referral for transplantation.

PMID: 27738125.

Abstract: Georgia has the lowest kidney transplant rates in the United States and substantial racial disparities in transplantation. We determined the effectiveness of a multicomponent intervention to increase referral of patients on dialysis for transplant evaluation in the Reducing Disparities in Access to kidNey Transplantation Community Study (RaDIANT), a randomized, dialysis facility-based, controlled trial involving >9000 patients receiving dialysis from 134 dialysis facilities in Georgia. In December of 2013, we selected dialysis facilities with either low transplant referral or racial disparity in referral. The intervention consisted of transplant education and engagement activities targeting dialysis facility leadership, staff, and patients conducted from January to December of 2014. We examined the proportion of patients with prevalent ESRD in each facility referred for transplant within 1 year as the primary outcome, and disparity in the referral of black and white patients as a secondary outcome. Compared with control facilities, intervention facilities referred a higher proportion of patients for transplant at

12 months (adjusted mean difference [aMD], 7.3%; 95% confidence interval [95% CI], 5.5% to 9.2%; odds ratio, 1.75; 95% CI, 1.36 to 2.26). The difference between intervention and control facilities in the proportion of patients referred for transplant was higher among black patients (aMD, 6.4%; 95% CI, 4.3% to 8.6%) than white patients (aMD, 3.7%; 95% CI, 1.6% to 5.9%; P<0.05). In conclusion, this intervention increased referral and improved equity in kidney transplant referral for patients on dialysis in Georgia; long-term follow-up is needed to determine whether these effects led to more transplants.

Patzer RE, Plantinga LC, Paul S, Gander J, Krisher J, Sauls L, Gibney EM, Mulloy L, Pastan SO. **Variation in Dialysis Facility Referral for Kidney Transplantation Among Patients With End-Stage Renal Disease in Georgia.** *JAMA. 2015 Aug 11;314(6):582-94. doi: 10.1001/jama.2015.8897.*

Notes: Study demonstrating wide facility level variation in referral for transplantation.

PMID: 26262796.

Abstract: Importance: Dialysis facilities in the United States are required to educate patients with end-stage renal disease about all treatment options, including kidney transplantation. Patients receiving dialysis typically require a referral for kidney transplant evaluation at a transplant center from a dialysis facility to start the transplantation process, but the proportion of patients referred for transplantation is unknown.

Objective: To describe variation in dialysis facility-level referral for kidney transplant evaluation and factors associated with referral among patients initiating dialysis in Georgia, the US state with the lowest kidney transplantation rates.

Design, setting, and participants: Examination of United States Renal Data System data from a cohort of 15,279 incident, adult (18-69 years) patients with end-stage renal disease from 308 Georgia dialysis facilities from January 2005 to September 2011, followed up through September 2012, linked to kidney transplant referral data collected from adult transplant centers in Georgia in the same period.

Main outcomes and measures: Referral for kidney transplant evaluation within 1 year of starting dialysis at any of the 3 Georgia transplant centers was the primary outcome; placement on the deceased donor waiting list was also examined.

Results: The median within-facility percentage of patients referred within 1 year of starting dialysis was 24.4% (interquartile range, 16.7%-33.3%) and varied from 0% to 75.0%. Facilities in the lowest tertile of referral (<19.2%) were more likely to treat patients living in high-poverty neighborhoods (absolute difference, 21.8% [95% CI, 14.1%-29.4%]), had a higher patient to social worker ratio (difference, 22.5 [95% CI, 9.7-35.2]), and were more likely nonprofit (difference, 17.6% [95% CI, 7.7%-27.4%]) compared with facilities in the highest tertile of referral (>31.3%). In multivariable, multilevel analyses, factors associated with lower referral for transplantation, such as older age, white race, and nonprofit facility status, were not always consistent with the factors associated with lower waitlisting.

Conclusions and relevance: In Georgia overall, a limited proportion of patients treated with dialysis were referred for kidney transplant evaluation between 2005 and 2011, but there was substantial variability in referral among facilities. Variables associated with referral were not always associated with waitlisting, suggesting that different factors may account for disparities in referral.

Paul S, Melanson T, Mohan S, Ross-Driscoll K, McPherson L, Lynch R, Lo D, Pastan SO, Patzer RE **Kidney transplant program waitlisting rate as a metric to assess transplant access.** *Am J Transplant. 2021 Jan;21(1):314-321. doi: 10.1111/ajt.16277. Epub 2020 Sep 15.*

Notes: Study describing a potential transplant center level metric (the waitlisting rate ratio) assessing access to transplantation.

PMID: 32808730.

Abstract: Kidney transplant program performance in the United States is commonly measured by posttransplant outcomes. Inclusion of pretransplant measures could provide a more comprehensive assessment of transplant program performance and necessary information for patient decision-making. In this study, we propose a new metric, the waitlisting rate, defined as the ratio of patients who are waitlisted in a center relative to the person-years referred for evaluation to a program. Furthermore, we standardize the waitlisting rate relative to the state average in Georgia, North Carolina, and South Carolina. The new metric was used as a proof-of-concept to assess transplant-program access compared to the existing transplant rate metric. The study cohorts were defined by linking 2017 United States Renal Data System (USRDS) data with transplant-program referral data from the Southeastern United States between January 1, 2012 and December 31, 2016. Waitlisting rate varied across the 9 Southeastern transplant programs, ranging from 10 to 22 events per 100 patient-years, whereas the program-specific waitlisting rate ratio ranged between 0.76 and 1.33. Program-specific waitlisting rate ratio was uncorrelated with the transplant rate ratio (r = -.15, 95% CI, -0.83 to 0.57). Findings warrant collection of national data on early transplant steps, such as referral, for a more comprehensive assessment of transplant program performance and pretransplant access.

Paul S, Plantinga LC, Pastan SO, Gander JC, Mohan S, Patzer RE. **Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities.** *Clin J Am Soc Nephrol. 2018 Feb 7;13(2):282-289. doi: 10.2215/CJN.04690417. Epub 2018 Jan 25.*

Notes: Description of a potential standardized transplant referral ratio measure for dialysis facilities.

PMID: 29371341.

Abstract: Background and objectives: For patients with ESRD, referral from a dialysis facility to a transplant center for evaluation is an important step toward kidney transplantation. However, a standardized measure for assessing clinical performance of dialysis facilities transplant access is lacking. We describe methodology for a new dialysis facility measure: the Standardized Transplantation Referral Ratio.

Design, setting, participants, & measurements: Transplant referral data from 8308 patients with incident ESRD within 249 dialysis facilities in the United States state of Georgia were linked with US Renal Data System data from January of 2008 to December of 2011, with follow-up through December of 2012. Facility-level expected referrals were computed from a two-stage Cox proportional hazards model after patient case mix risk adjustment including demographics and comorbidities. The Standardized Transplantation Referral Ratio (95% confidence interval) was calculated as a ratio of observed to expected referrals. Measure validity and reliability were assessed.

Results: Over 2008-2011, facility Standardized Transplantation Referral Ratios in Georgia ranged from 0 to 4.87 (mean =1.16, SD=0.76). Most (77%) facilities had observed referrals as expected, whereas 11% and 12% had Standardized Transplantation Referral Ratios significantly greater than and less than expected, respectively. Age, race, sex, and comorbid conditions were significantly associated with the likelihood of referral, and they were included in risk adjustment for Standardized Transplantation Referral Ratio calculations. The Standardized Transplantation Referral Ratios were positively associated with evaluation, waitlisting, and transplantation (r=0.46, 0.35, and 0.20, respectively; P<0.01). On average, approximately 33% of the variability in Standardized Transplantation Referral Ratios was attributed to between-facility variation, and 67% of the variability in Standardized Transplantation Referral Ratios was attributed to within-facility variation.

Conclusions: The majority of observed variation in dialysis facility referral performance was due to characteristics within a dialysis facility rather than patient factors included in risk adjustment models. Our study shows a method for computing a facility-level standardized measure for transplant referral on the basis of a pilot sample of Georgia dialysis facilities that could be used to monitor transplant referral performance of dialysis facilities.

Peipert JD, Hays RD, Kawakita S, Beaumont JL, Waterman AD. **Measurement Characteristics of the Knowledge Assessment of Renal Transplantation.** *Transplantation. 2019 Mar;103(3):565-572. doi: 10.1097/TP.0000000000002349.*

Notes: Study describing development and validation of the Knowledge Assessement of Renal Transplantation (KART) instrument in ESRD patients.

PMID: 29965952.

Abstract: Background: Kidney transplant is the best treatment for most end-stage renal disease (ESRD) patients, but proportionally few ESRD patients receive kidney transplant. To make an informed choice about whether to pursue kidney transplant, patients must be knowledgeable of its risks and benefits. To reliably and validly measure ESRD patients' kidney transplant knowledge, rigorously tested measures are required. This article describes the development and psychometric testing of the Knowledge Assessment of Renal Transplantation (KART).

Methods: We administered 17 transplant knowledge items to a sample of 1294 ESRD patients. Item characteristics and scale scores were estimated using an Item Response Theory graded response model. Construct validity was tested by examining differences in scale scores between patients who had spent less than 1 and 1 hour or longer receiving various types of transplant education.

Results: Item Response Theory modeling suggested that 15 items should be retained for the KART. This scale had a marginal reliability of 0.75 and evidenced acceptable reliability (>0.70) across most of its range. Construct validity was supported by the KART's ability to distinguish patients who had spent less than 1 and 1 hour or longer receiving different types of kidney transplant education, including talking to doctors/medical staff (effect size [ES], 0.61; P < 0.001), reading brochures (ES, 0.45; P < 0.001), browsing the internet (ES, 0.56; P < 0.001), and watching videos (ES, 0.56; P < 0.001).

Conclusions: The final 15-item KART can be used to determine the kidney transplant knowledge levels of ESRD patients and plan appropriate interventions to ensure informed transplant decision making occurs.

Plantinga LC, Lynch RJ, Patzer RE, Pastan SO, Bowling CB. **Association of Serious Fall Injuries among United States End Stage Kidney Disease Patients with Access to Kidney Transplantation.** *Clin J Am Soc Nephrol. 2018 Apr 6;13(4):628-637. doi: 10.2215/CJN.10330917. Epub 2018 Mar 6.*

PMID: 29511059.

Abstract: Background and objectives: Serious fall injuries in the setting of ESKD may be associated with poor access to kidney transplant. We explored the burden of serious fall injuries among patients on dialysis and patients on the deceased donor waitlist and the associations of these fall injuries with waitlisting and transplantation.

Design, setting, participants, & measurements: Our analytic cohorts for the outcomes of (1) waitlisting and (2) transplantation included United States adults ages 18-80 years old who (1) initiated dialysis (n=183,047) and (2) were waitlisted for the first time (n=37,752) in 2010-2013. Serious fall injuries were determined by diagnostic codes for falls plus injury (fracture, joint dislocation, or head trauma) in inpatient and emergency department claims; the first serious fall injury after cohort entry was included as a time-varying exposure. Follow-up ended at the specified outcome, death, or the last date of follow-up (September 30, 2014). We used multivariable Cox proportional hazards models to determine the independent associations between serious fall injury and waitlisting or transplantation.

Results: Overall, 2-year cumulative incidence of serious fall injury was 6% among patients on incident dialysis; with adjustment, patients who had serious fall injuries were 61% less likely to be waitlisted than patients who did not (hazard ratio, 0.39; 95% confidence interval, 0.35 to 0.44). Among incident waitlisted patients (4% 2-year cumulative incidence), those with serious fall injuries were 29% less likely than their counterparts to be subsequently transplanted (hazard ratio, 0.71; 95% confidence interval, 0.63 to 0.80).

Conclusions: Serious fall injuries among United States patients on dialysis are associated with substantially lower likelihood of waitlisting for and receipt of a kidney transplant.

Plantinga LC, Pastan SO, Wilk AS, Krisher J, Mulloy L, Gibney EM, Patzer RE. **Referral for Kidney Transplantation and Indicators of Quality of Dialysis Care: A Cross-sectional Study.** *Am J Kidney Dis. 2017 Feb;69(2):257-265. doi: 10.1053/j.ajkd.2016.08.038. Epub 2016 Nov 20.*

PMID: 27881246.

Abstract: Background: Dialysis facility performance measures to improve access to kidney transplantation are being considered. Referral of patients for kidney transplantation evaluation by the dialysis facility is one potential indicator, but limited data exist to evaluate whether referral is associated with existing dialysis facility quality indicators.

Study design: Cross-sectional study.

Setting & participants: 12,926 incident (July 2005 to September 2011) adult (aged 18-69 years) patients treated at 241 dialysis facilities with complete quality indicator information from US national registry data linked to transplantation referral data from all 3 Georgia kidney transplantation centers.

Factors: Facility performance on dialysis quality indicators (high, intermediate, and low tertiles).

Outcome: Percentages of patients referred within 1 year of dialysis therapy initiation at dialysis facility.

Results: Overall, a median of 25.4% of patients were referred for kidney transplantation within 1 year of dialysis therapy initiation. Higher facility-level referral was associated with better performance with respect to standardized transplantation ratio (high, 28.6%; intermediate, 25.1%; and low, 22.9%; P=0.001) and percentage waitlisted (high, 30.7%; intermediate, 26.8%; and low, 19.2%; P<0.001). Facility-level referral was not associated with indicators of quality of care associated with dialysis therapy initiation, including percentage of incident patients being informed of transplantation options. For most non-transplantation-related indicators of high-quality care, including those capturing mortality, morbidity, and anemia management, better performance was not associated with higher facility-level transplantation referral.

Limitations: Potential ecologic fallacy and residual confounding.

Conclusions: Transplantation referral among patients at dialysis facilities does not appear to be associated with overall quality of dialysis care at the facility. Quality indicators related to kidney transplantation were positively associated with, but not entirely correspondent with, higher percentages of patients referred for kidney transplantation evaluation from dialysis facilities. These results suggest that facility-level referral, which is within the control of the dialysis facility, may provide information about the quality of dialysis care beyond current indicators.

Purnell TS, Luo X, Cooper LA, Massie AB, Kucirka LM, Henderson ML, Gordon EJ, Crews DC, Boulware LE, Segev DL. **Association of Race and Ethnicity With Live Donor Kidney Transplantation in the United States From 1995 to 2014.** *JAMA. 2018 Jan 2;319(1):49-61. doi: 10.1001/jama.2017.19152.*

Notes: Study describing racial disparities in access to living kidney donor transplantation.

PMID: 29297077.

Abstract: Importance: Over the past 2 decades, there has been increased attention and effort to reduce disparities in live donor kidney transplantation (LDKT) for black, Hispanic, and Asian patients with end-stage kidney disease. The goal of this study was to investigate whether these efforts have been successful.

Objective: To estimate changes over time in racial/ethnic disparities in LDKT in the United States, accounting for differences in death and deceased donor kidney transplantation.

Design, setting, and participants: A secondary analysis of a prospectively maintained cohort study conducted in the United States of 453 162 adult first-time kidney transplantation candidates included in the Scientific Registry of Transplant Recipients between January 1, 1995, and December 31, 2014, with follow-up through December 31, 2016.

Exposures: Race/ethnicity.

Main outcomes and measures: The primary study outcome was time to LDKT. Multivariable Cox proportional hazards and competing risk models were constructed to assess changes in racial/ethnic disparities in LDKT among adults on the deceased donor kidney transplantation waiting list and interaction terms were used to test the statistical significance of temporal changes in racial/ethnic differences in receipt of LDKT. The adjusted subhazard ratios are estimates derived from the multivariable competing risk models. Data were categorized into 5-year increments (1995-1999, 2000-2004, 2005-2009, 2010-2014) to allow for an adequate sample size in each analytical cell.

Results: Among 453 162 adult kidney transplantation candidates (mean [SD] age, 50.9 [13.1] years; 39% were women; 48% were white; 30%, black; 16%, Hispanic; and 6%, Asian), 59 516 (13.1%) received LDKT. Overall, there were 39 509 LDKTs among white patients, 8926 among black patients, 8357 among Hispanic patients, and 2724 among Asian patients. In 1995, the cumulative incidence of LDKT at 2 years after appearing on the waiting list was 7.0% among white patients, 3.4% among black patients, 6.8% among Hispanic patients, and 5.1% among

Asian patients. In 2014, the cumulative incidence of LDKT was 11.4% among white patients, 2.9% among black patients, 5.9% among Hispanic patients, and 5.6% among Asian patients. From 1995-1999 to 2010-2014, racial/ethnic disparities in the receipt of LDKT increased (P < .001 for all statistical interaction terms in adjusted models comparing white patients vs black, Hispanic, and Asian patients). In 1995-1999, compared with receipt of LDKT among white patients, the adjusted subhazard ratio was 0.45 (95% CI, 0.42-0.48) among black patients, 0.83 (95% CI, 0.77-0.88) among Hispanic patients, and 0.56 (95% CI, 0.50-0.63) among Asian patients. In 2010-2014, compared with receipt of LDKT among white patients, the adjusted subhazard ratio was 0.27 (95% CI, 0.26-0.28) among black patients, 0.52 (95% CI, 0.50-0.54) among Hispanic patients, and 0.42 (95% CI, 0.39-0.45) among Asian patients.

Conclusions and relevance: Among adult first-time kidney transplantation candidates in the United States who were added to the deceased donor kidney transplantation waiting list between 1995 and 2014, disparities in the receipt of live donor kidney transplantation increased from 1995-1999 to 2010-2014. These findings suggest that national strategies for addressing disparities in receipt of live donor kidney transplantation should be revisited.

Purnell TS, Luo X, Kucirka LM, Cooper LA, Crews DC, Massie AB, Boulware LE, Segev DL. **Reduced Racial Disparity in Kidney Transplant Outcomes in the United States from 1990 to 2012.** *J Am Soc Nephrol. 2016 Aug;27(8):2511-8. doi: 10.1681/ASN.2015030293. Epub 2016 Feb 4.*

PMID: 26848153.

Abstract: Earlier studies reported inferior outcomes among black compared with white kidney transplant (KT) recipients. We examined whether this disparity improved in recent decades. Using the Scientific Registry of Transplant Recipients and Cox regression models, we compared all-cause graft loss among 63,910 black and 145,482 white adults who received a first-time live donor KT (LDKT) or deceased donor KT (DDKT) in 1990-2012. Over this period, 5-year graft loss after DDKT improved from 51.4% to 30.6% for blacks and from 37.3% to 25.0% for whites; 5-year graft loss after LDKT improved from 37.4% to 22.2% for blacks and from 20.8% to 13.9% for whites. Among DDKT recipients in the earliest cohort, blacks were 39% more likely than whites to experience 5-year graft loss (adjusted hazard ratio [aHR], 1.39; 95% confidence interval [95% CI], 1.32 to 1.47; P<0.001), but this disparity narrowed in the most recent cohort (aHR, 1.10; 95% CI, 1.03 to 1.18; P=0.01). Among LDKT recipients in the earliest cohort, blacks were 53% more likely than whites to experience 5-year graft loss (aHR, 1.53; 95% CI, 1.27 to 1.83; P<0.001), but this disparity also narrowed in the most recent cohort (aHR, 1.37; 95% CI, 1.17 to 1.61; P<0.001). Analyses revealed no statistically significant differences in 1-year or 3-year graft loss after LDKT or DDKT in the most recent cohorts. Our findings of reduced disparities over the last 22 years driven by more markedly improved outcomes for blacks may encourage nephrologists and patients to aggressively promote access to transplantation in the black community.

Reed RD, Hites L, Mustian MN, Shelton BA, Hendricks D, Berry B, MacLennan PA, Blackburn J, Wingate MS, Yates C, Hannon L, Kilgore ML, Locke JE. **A Qualitative Assessment of the Living Donor Navigator Program to Identify Core Competencies and Promising Practices for Implementation.** *Prog Transplant. 2020 Mar;30(1):29-37. doi: 10.1177/1526924819892919. Epub 2019 Dec 16.*

PMID: 31838948.

Abstract: Introduction: The best strategy to increase awareness of and access to living kidney donation remains unknown. To build upon the existing strategies, we developed the Living Donor Navigator program, combining advocacy training of patient advocates with enhanced health-care systems training of patient navigators to address potential living donor concerns during the evaluation process. Herein, we describe a systematic assessment of the delivery and content of the program through focus group discussion.

Methods: We conducted focus groups with 9 advocate participants in the Living Donor Navigator program to identify knowledge, skills, and abilities needed for both advocates and navigators. We focused on 2 organizational levels: (1) the participant level or the advocacy training of the advocates and (2) the programmatic level or the support role provided by the navigators and administration of the program.

Findings: From 4 common themes (communication, education, support, and commitment), we identified several core competencies and promising practices, at both the participant and programmatic levels. These themes highlighted the potential for several improvements of program content and delivery, the importance of cultural sensitivity among the Living Donor navigators, and the opportunity for informal caregiver support and accountability provided by the program.

Discussion: These competencies and promising practices represent actionable strategies for content refinement, optimal training of advocates, and engagement of potential living donors through the Living Donor Navigator program. These findings may also assist with program implementation at other transplant centers in the future.

Reed RD, Shelton BA, Mustian MN, MacLennan PA, Sawinski D, Locke JE. **Geographic Differences in Population Health and Expected Organ Supply in the Gulf Coast Region of the United States Compared to Non-Gulf States.** *Transplantation. 2020 Feb;104(2):421-427. doi: 10.1097/TP.0000000000002831.*

PMID: 32004235.

Abstract: Background: The Final Rule aimed to reduce geographic disparities in access to transplantation by prioritizing the need for transplant over donor proximity. However, disparities in waiting times persist for deceased donor kidney transplantation. The kidney allocation system implemented in 2014 does not account for potential local supply based on population health characteristics within a donation service area (DSA). We hypothesized that regions with traditionally high rates of comorbid disease, such as the states located along the

Gulf of Mexico (Gulf States), may be disadvantaged by limited local supply secondary to poor population health.

Methods: Using data from the Robert Wood Johnson Foundation County Health Rankings, the United States Renal Data System, and the Scientific Registry of Transplant Recipients, we compared population-level characteristics and expected kidney donation rates by Gulf States location.

Results: Prevalence of African American ethnicity, end-stage renal disease, diabetes, fair/poor self-rated health, physical inactivity, food insecurity, and uninsurance were higher among Gulf State DSAs. On unadjusted analyses, Gulf State DSAs were associated with 3.52 fewer expected kidney donors per 100 eligible deaths than non-Gulf States. After adjustment, there was no longer a statistically significant difference in expected kidney donation rate.

Conclusions: Although Gulf State DSAs have lower expected donation rates, these differences appear to be driven by the prevalence of health factors negatively associated with donation rate. These data suggest the need to discuss population health characteristics when examining kidney allocation policy, to account for potential lower supply of donors and to further address geographic disparities in access to kidney transplantation.

Rodrigue JR, Kazley AS, Mandelbrot DA, Hays R, LaPointe Rudow D, Baliga P; American Society of Transplantation. **Living Donor Kidney Transplantation: Overcoming Disparities in Live Kidney Donation in the US--Recommendations from a Consensus Conference.** *Clin J Am Soc Nephrol. 2015 Sep 4;10(9):1687-95. doi: 10.2215/CJN.00700115. Epub 2015 Apr 16.*

PMID: 25883072.

Abstract: Despite its superior outcomes relative to chronic dialysis and deceased donor kidney transplantation, live donor kidney transplantation (LDKT) is less likely to occur in minorities, older adults, and poor patients than in those who are white, younger, and have higher household income. In addition, there is considerable geographic variability in LDKT rates. Concomitantly, in recent years, the rate of living kidney donation (LKD) has stopped increasing and is declining, after decades of consistent growth. Particularly noteworthy is the decline in LKD among black, younger, male, and lower-income adults. The Live Donor Community of Practice within the American Society of Transplantation, with financial support from 10 other organizations, held a Consensus Conference on Best Practices in Live Kidney Donation in June 2014. The purpose of this meeting was to identify LKD best practices and knowledge gaps that might influence LDKT, with a focus on patient and donor education, evaluation efficiencies, disparities, and systemic barriers to LKD. In this article, we discuss trends in LDKT/LKD and emerging novel strategies for attenuating disparities, and we offer specific recommendations for future clinical practice, education, research, and policy from the Consensus Conference Workgroup focused on disparities.

Ross-Driscoll K, Axelrod D, Lynch R, Patzer RE. **Using Geographic Catchment Areas to Measure Population-based Access to Kidney Transplant in the United States.** *Transplantation. 2020 Dec;104(12):e342-e350. doi: 10.1097/TP.0000000000003369.*

PMID: 33215901.

Abstract: Background: Monitoring efforts to improve access to transplantation requires a definition of the population attributable to a transplant center. Previously, assessment of variation in transplant care has focused on differences between administrative units-such as states-rather than units derived from observed care patterns. We defined catchment areas (transplant referral regions [TRRs]) from transplant center care patterns for population-based assessment of transplant access.

Methods: We used US adult transplant listings (2006-2016) and Dartmouth Atlas catchment areas to assess the optimal method of defining TRRs. We used US Renal Data System and Scientific Registry of Transplant Recipient data to compare waitlist- and population-based kidney transplant rates.

Results: We identified 110 kidney, 67 liver, 85 pancreas, 68 heart, and 43 lung TRRs. Most patients were listed in their assigned TRR (kidney: 76%; liver: 75%; pancreas: 75%; heart: 74%; lung: 72%), although the proportion varied by organ (interquartile range for kidney, 65.7%-82.5%; liver, 58.2%-78.8%; pancreas, 58.4%-81.1%; heart, 63.1%-80.9%; lung, 61.6%-76.3%). Patterns of population- and waitlist-based kidney transplant rates differed, most notably in the Northeast and Midwest.

Conclusions: Patterns of TRR-based kidney transplant rates differ from waitlist-based rates, indicating that current metrics may not reflect transplant access in the broader population. TRRs define populations served by transplant centers and could enable future studies of how transplant centers can improve access for patients in their communities.

Salter ML, Kumar K, Law AH, Gupta N, Marks K, Balhara K, McAdams-DeMarco MA, Taylor LA, Segev DL. **Perceptions about hemodialysis and transplantation among African American adults with end-stage renal disease: inferences from focus groups.** *BMC Nephrol. 2015 Apr 9;16:49. doi: 10.1186/s12882-015-0045-1.*

PMID: 25881073.

Abstract: Background: Disparities in access to kidney transplantation (KT) remain inadequately understood and addressed. Detailed descriptions of patient attitudes may provide insight into mechanisms of disparity. The aims of this study were to explore perceptions of dialysis and KT among African American adults undergoing hemodialysis, with particular attention to age- and sex-specific concerns.

Methods: Qualitative data on experiences with hemodialysis and views about KT were collected through four age- and sex-stratified (males <65, males ≥65, females <65, and females ≥65 years) focus group discussions with 36 African American adults recruited from seven urban dialysis centers in Baltimore, Maryland.

Results: Four themes emerged from thematic content analysis: 1) current health and perceptions of dialysis, 2) support while undergoing dialysis, 3) interactions with medical professionals, and 4) concerns about KT. Females and older males tended to be more positive about dialysis experiences. Younger males expressed a lack of support from friends and family. All participants shared feelings of being treated poorly by medical professionals and lacking information about renal disease and treatment options. Common concerns about pursuing KT were increased medication burden, fear of surgery, fear of organ rejection, and older age (among older participants).

Conclusions: These perceptions may contribute to disparities in access to KT, motivating granular studies based on the themes identified.

Salter ML, Orandi B, McAdams-DeMarco MA, Law A, Meoni LA, Jaar BG, Sozio SM, Kao WH, Parekh RS, Segev DL **Patient- and provider-reported information about transplantation and subsequent waitlisting.** *J Am Soc Nephrol. 2014 Dec;25(12):2871-7. doi: 10.1681/ASN.2013121298. Epub 2014 Aug 28.*

PMID: 25168028.

Abstract: Because informed consent requires discussion of alternative treatments, proper consent for dialysis should incorporate discussion about other renal replacement options including kidney transplantation (KT). Accordingly, dialysis providers are required to indicate KT provision of information (KTPI) on CMS Form-2728; however, provider-reported KTPI does not necessarily imply adequate provision of information. Furthermore, the effect of KTPI on pursuit of KT remains unclear. We compared provider-reported KTPI (Form-2728) with patient-reported KTPI (in-person survey of whether a nephrologist or dialysis staff had discussed KT) in a prospective ancillary study of 388 hemodialysis initiates. KTPI was reported by both patient and provider for 56.2% of participants, by provider only for 27.8%, by patient only for 8.3%, and by neither for 7.7%. Among participants with provider-reported KTPI, older age was associated with lack of patient-reported KTPI. Linkage with the Scientific Registry for Transplant Recipients showed that 20.9% of participants were subsequently listed for KT. Patient-reported KTPI was independently associated with a 2.95-fold (95% confidence interval [95% CI], 1.54 to 5.66; P=0.001) higher likelihood of KT listing, whereas provider-reported KTPI was not associated with listing (hazard ratio, 1.18; 95% CI, 0.60 to 2.32; P=0.62). Our findings suggest that patient perception of KTPI is more important for KT listing than provider-reported KTPI. Patient-reported and provider-reported KTPI should be collected for quality assessment in dialysis centers because factors associated with discordance between these metrics might inform interventions to improve this process.

Saunders MR, Lee H, Alexander GC, Tak HJ, Thistlethwaite JR Jr, Ross LF. **Racial disparities in reaching the renal transplant waitlist: is geography as important as race?.** *Clin Transplant. 2015 Jun;29(6):531-8. doi: 10.1111/ctr.12547. Epub 2015 Apr 27.*

PMID: 25818547.

Abstract: Background: In the United States, African Americans and whites differ in access to the deceased donor renal transplant waitlist. The extent to which racial disparities in waitlisting differ between United Network for Organ Sharing (UNOS) regions is understudied.

Methods: The US Renal Data System (USRDS) was linked with US census data to examine time from dialysis initiation to waitlisting for whites (n = 188,410) and African Americans (n = 144,335) using Cox proportional hazards across 11 UNOS regions, adjusting for potentially confounding individual, neighborhood, and state characteristics.

Results: Likelihood of waitlisting varies significantly by UNOS region, overall and by race. Additionally, African Americans face significantly lower likelihood of waitlisting compared to whites in all but two regions (1 and 6). Overall, 39% of African Americans with ESRD reside in Regions 3 and 4--regions with a large racial disparity and where African Americans comprise a large proportion of the ESRD population. In these regions, the African American-white disparity is an important contributor to their overall regional disparity.

Conclusions: Race remains an important factor in time to transplant waitlist in the United States. Race contributes to overall regional disparities; however, the importance of race varies by UNOS region.

Schold JD, Mohan S, Huml A, Buccini LD, Sedor JR, Augustine JJ, Poggio ED **Failure to Advance Access to Kidney Transplantation over Two Decades in the United States.** *J Am Soc Nephrol. 2021 Feb 11;ASN.2020060888. doi: 10.1681/ASN.2020060888.*

Notes: Large national study describing patterns of access to transplantation over the last 2 decades.

PMID: 33574159.

Abstract: Background: Extensive research and policies have been developed to improve access to kidney transplantation among patients with ESKD. Despite this, wide variation in transplant referral rates exists between dialysis facilities. Methods: To evaluate the longitudinal pattern of access to kidney transplantation over the past two decades, we conducted a retrospective cohort study of adult patients with ESKD initiating ESKD or placed on a transplant waiting list from 1997 to 2016 in the United States Renal Data System. We used cumulative incidence models accounting for competing risks and multivariable Cox models to evaluate time to waiting list placement or transplantation (WLT) from ESKD onset. Results: Among the study population of 1,309,998 adult patients, cumulative 4-year WLT was 29.7%, which was unchanged over five eras. Preemptive WLT (prior to dialysis) increased by era (5.2% in 1997-2000 to 9.8% in 2013-

2016), as did 4-year WLT incidence among patients aged 60-70 (13.4% in 1997-2000 to 19.8% in 2013-2016). Four-year WLT incidence diminished among patients aged 18-39 (55.8%-48.8%). Incidence of WLT was substantially lower among patients in lower-income communities, with no improvement over time. Likelihood of WLT after dialysis significantly declined over time (adjusted hazard ratio, 0.80; 95% confidence interval, 0.79 to 0.82) in 2013-2016 relative to 1997-2000. Conclusions: Despite wide recognition, policy reforms, and extensive research, rates of WLT following ESKD onset did not seem to improve in more than two decades and were consistently reduced among vulnerable populations. Improving access to transplantation may require more substantial interventions.

Schold, J D & Heaphy, E L G & Buccini, L D & Poggio, E D & Srinivas, T R & Goldfarb, D A & Flechner, S M & Rodrigue, J R & Thornton, J D & Sehgal, A R **Prominent impact of community risk factors on kidney transplant candidate processes and outcomes.** *Am J Transplant. 2013 Sep;13(9):2374-83. doi: 10.1111/ajt.12349. Epub 2013 Aug 22.*

PMID: 24034708.

Abstract: Numerous factors impact patients' health beyond traditional clinical characteristics. We evaluated the association of risk factors in kidney transplant patients' communities with outcomes prior to transplantation. The primary exposure variable was a community risk score (range 0-40) derived from multiple databases and defined by factors including prevalence of comorbidities, access and quality of healthcare, self-reported physical and mental health and socioeconomic status for each U.S. county. We merged data with the Scientific Registry of Transplant Recipients (SRTR) and utilized risk-adjusted models to evaluate effects of community risk for adult candidates listed 2004-2010 (n = 209 198). Patients in highest risk communities were associated with increased mortality (adjusted hazard ratio [AHR] = 1.22, 1.16-1.28), decreased likelihood of living donor transplantation (adjusted odds ratio [AOR] = 0.90, 0.85-0.94), increased waitlist removal for health deterioration (AHR = 1.36, 1.22-1.51), decreased likelihood of preemptive listing (AOR = 0.85, 0.81-0.88), increased likelihood of inactive listing (AOR = 1.49, 1.43-1.55) and increased likelihood of listing for expanded criteria donor kidneys (AHR = 1.19, 1.15-1.24). Associations persisted with adjustment for rural-urban location; furthermore the independent effects of rural-urban location were largely eliminated with adjustment for community risk. Average community risk varied widely by region and transplant center (median = 21, range 5-37). Community risks are powerful factors associated with processes of care and outcomes for transplant candidates and may be important considerations for developing effective interventions and measuring quality of care of transplant centers.

Stewart DE, Kucheryavaya AY, Klassen DK, Turgeon NA, Formica RN, Aeder MI. **Changes in Deceased Donor Kidney Transplantation One Year After KAS Implementation.** *Am J Transplant. 2016 Jun;16(6):1834-47. doi: 10.1111/ajt.13770. Epub 2016 Mar 31.*

PMID: 26932731.

Abstract: After over a decade of discussion, analysis, and consensus-building, a new kidney allocation system (KAS) was implemented on December 4, 2014. Key goals included improving longevity matching between donor kidneys and recipients and broadening access for historically disadvantaged subpopulations, in particular highly sensitized patients and those with an extended duration on dialysis but delayed referral for transplantation. To evaluate the early impact of KAS, we compared Organ Procurement and Transplantation Network data 1 year before versus after implementation. The distribution of transplants across many recipient characteristics has changed markedly and suggests that in many ways the new policy is achieving its goals. Transplants in which the donor and recipient age differed by more than 30 years declined by 23%. Initial, sharp increases in transplants were observed for Calculated Panel-Reactive Antibody 99-100% recipients and recipients with at least 10 years on dialysis, with a subsequent tapering of transplants to these groups suggesting bolus effects. Although KAS has arguably increased fairness in allocation, the potential costs of broadening access must be considered. Kidneys are more often being shipped over long distances, leading to increased cold ischemic times. Delayed graft function rates have increased, but 6-month graft survival rates have not changed significantly.

Sullivan CM, Barnswell KV, Greenway K, Kamps CM, Wilson D, Albert JM, Dolata J, Huml A, Pencak JA, Ducker JT, Gedaly R, Jones CM, Pesavento T, Sehgal AR. **Impact of Navigators on First Visit to a Transplant Center, Waitlisting, and Kidney Transplantation: A Randomized, Controlled Trial.** *Clin J Am Soc Nephrol. 2018 Oct 8;13(10):1550-1555. doi: 10.2215/CJN.03100318. Epub 2018 Aug 22.*

Notes: Cluster randomized trial of patient navigator intervention on access to transplantation.

PMID: 30135171.

Abstract: Background and objectives: Many patients with ESKD face barriers in completing the steps required to obtain a transplant. These eight sequential steps are medical suitability, interest in transplant, referral to a transplant center, first visit to center, transplant workup, successful candidate, waiting list or identify living donor, and receive transplant. This study sought to determine the effect of navigators on helping patients complete these steps.

Design, setting, participants, & measurements: Our study was a cluster randomized, controlled trial involving 40 hemodialysis facilities and four transplant centers in Ohio, Kentucky, and Indiana from January 1, 2014 to December 31, 2016. Four trained kidney transplant recipients met regularly with patients on hemodialysis at 20 intervention facilities, determined their step in the transplant process, and provided tailored information and assistance in completing that step and subsequent steps. Patients at 20 control facilities continued to receive usual care. Primary study outcomes were waiting list placement and receipt of a deceased or living donor transplant. An exploratory outcome was first visit to a transplant center.

Results: Before the trial, intervention (1041 patients) and control (836 patients) groups were similar in the proportions of patients who made a first visit to a transplant center, were placed on a waiting list, and received a deceased or living donor transplant. At the end of the trial, intervention and control groups were also similar in first visit (16.1% versus 13.8%; difference, 2.3%; 95% confidence interval, -0.8% to 5.5%), waitlisting (16.3% versus 13.8%; difference, 2.5%; 95% confidence interval, -1.2% to 6.1%), deceased donor transplantation (2.8% versus 2.2%; difference, 0.6%; 95% confidence interval, -0.8% to 2.1%), and living donor transplantation (1.2% versus 1.0%; difference, 0.1%; 95% confidence interval, -0.9% to 1.1%).

Conclusions: Use of trained kidney transplant recipients as navigators did not increase first visits to a transplant center, waiting list placement, and receipt of deceased or living donor transplants.

Taber DJ, Gebregziabher M, Hunt KJ, Srinivas T, Chavin KD, Baliga PK, Egede LE. **Twenty years of evolving trends in racial disparities for adult kidney transplant recipients.** *Kidney Int. 2016 Oct;90(4):878-87. doi: 10.1016/j.kint.2016.06.029. Epub 2016 Aug 20.*

PMID: 27555121.

Abstract: Disparities in outcomes for African American (AA) kidney transplant recipients have persisted for 40 years without a comprehensive analysis of evolving trends in the risks associated with this disparity. Here we analyzed U.S. transplant registry data, which included adult Caucasian or AA solitary kidney recipients undergoing transplantation between 1990 and 2009 comprising 202,085 transplantations. During this 20-year period, the estimated rate of 5-year graft loss decreased from 27.6% to 12.8%. Notable trends in baseline characteristics that significantly differed by race over time included the following: increased prevalence of diabetes from 2001 to 2009 in AAs (5-year slope difference: 3.4%), longer time on the waiting list (76.5 more days per 5 years in AAs), fewer living donors in AAs from 2003 to 2009 (5-year slope difference: -3.36%), more circulatory death donors in AAs from 2000-09 (5-year slope difference: 1.78%), and a slower decline in delayed graft function in AAs (5-year slope difference: 0.85%). The absolute risk difference between AAs and Caucasians for 5-year graft loss significantly declined over time (-0.92% decrease per 5 years), whereas the relative risk difference actually significantly increased (3.4% increase per 5 years). These results provide a mixed picture of both promising and concerning trends in disparities for AA kidney transplant recipients. Thus, although the disparity for graft loss has significantly improved, equity is still far off, and other disparities, including living donation rates and delayed graft function rates, have widened during this time.

Talamantes E, Norris KC, Mangione CM, Moreno G, Waterman AD, Peipert JD, Bunnapradist S, Huang E. **Linguistic Isolation and Access to the Active Kidney Transplant Waiting List in the United States.** *Clin J Am Soc Nephrol. 2017 Mar 7;12(3):483-492. doi: 10.2215/CJN.07150716. Epub 2017 Feb 9.*

PMID: 28183854.

Abstract: Background and objectives: Waitlist inactivity is a barrier to transplantation, because inactive candidates cannot receive deceased donor organ offers. We hypothesized that temporarily inactive kidney transplant candidates living in linguistically isolated communities would be less likely to achieve active waitlist status.

Design, setting, participants, & measurements: We merged Organ Procurement and Transplantation Network/United Network for Organ Sharing data with five-digit zip code socioeconomic data from the 2000 US Census. The cumulative incidence of conversion to active waitlist status, death, and delisting before conversion among 84,783 temporarily inactive adult kidney candidates from 2004 to 2012 was determined using competing risks methods. Competing risks regression was performed to characterize the association between linguistic isolation, incomplete transplantation evaluation, and conversion to active status. A household was determined to be linguistically isolated if all members ≥14 years old speak a non-English language and also, speak English less than very well.

Results: A total of 59,147 candidates (70% of the study population) achieved active status over the study period of 9.8 years. Median follow-up was 110 days (interquartile range, 42-276 days) for activated patients and 815 days (interquartile range, 361-1244 days) for candidates not activated. The cumulative incidence of activation over the study period was 74%, the cumulative incidence of death before conversion was 10%, and the cumulative incidence of delisting was 13%. After adjusting for other relevant covariates, living in a zip code with higher percentages of linguistically isolated households was associated with progressively lower subhazards of activation both in the overall population (reference: <1% linguistically isolated households; 1%-4.9% linguistically isolated: subhazard ratio, 0.89; 95% confidence interval, 0.86 to 0.93; 5%-9.9% linguistically isolated: subhazard ratio, 0.83; 95% confidence interval, 0.80 to 0.87; 10%-19.9% linguistically isolated: subhazard ratio, 0.76; 95% confidence interval, 0.72 to 0.80; and ≥20% linguistically isolated: subhazard ratio, 0.71; 95% confidence interval, 0.67 to 0.76) and among candidates designated temporarily inactive due to an incomplete transplant evaluation.

Conclusions: Our findings indicate that candidates residing in linguistically isolated communities are less likely to complete candidate evaluations and achieve active waitlist status.

Tang E, Bansal A, Famure O, Keszei A, Novak M, Kim SJ, Mucsi I. **Substance use in kidney transplant candidates and its impact on access to kidney transplantation.** *Clin Transplant. 2019 Jun;33(6):e13565. doi: 10.1111/ctr.13565. Epub 2019 May 7.*

PMID: 31002182.

Abstract: Background: Due to the increasing public acceptance of substance use, it is important to understand the association between substance use and access to kidney transplant and its outcomes. Here, we assess the sociodemographic predictors of substance use and the association between substance use and KT access.

Methods: Predictors of substance use were examined using a multivariable-adjusted multinomial logistic regression. The association between current substance use (tobacco and drug) and time from referral to listing or receipt of a KT was examined using Cox proportional hazards models.

Results: Of 2346 patients, the prevalence of current substance use was 17%. Predictors of current tobacco use were younger age, male sex, Caucasian ethnicity, being unemployed, and unmarried. Predictors of current drug use were younger age, male sex, Caucasian ethnicity, a history of non-adherence, and a history of mental health disorder. Patients with tobacco use had a decreased likelihood of being cleared for KT (hazard ratio [HR]:0.83[0.70, 0.99]) and receiving a KT (HR:0.80 [0.66, 0.96]). No association was seen in this sample for patients with drug use (HR:0.88 [0.69, 1.11] for being cleared for KT and 0.88 [0.69, 1.14] for KT, respectively).

Conclusions: Tobacco use was associated with a decreased likelihood of access to KT whereas there was no statistically significant difference in access to KT between patients with or without drug use.

Virmani S, Asch WS. **The Role of the General Nephrologist in Evaluating Patients for Kidney Transplantation: Core Curriculum 2020.** *Am J Kidney Dis. 2020 Oct;76(4):567-579. doi: 10.1053/j.ajkd.2020.01.001. Epub 2020 Mar 19.*

Notes: Review article discussing role of general nephrologist in evaluation of patients for kidney transplantation.

PMID: 32199707.

Abstract: Transplantation is the preferred modality of replacement therapy for most patients with kidney failure. In the United States, more than 3,000 new patients are registered each month on the kidney transplant waiting list for this life-saving therapy. A potential kidney transplant recipient's evaluation typically begins with a referral by the general nephrologist to a transplantation center. In this installment in the Core Curriculum in Nephrology, we endeavor to achieve a shared understanding of the patient factors that contribute to optimal patient and allograft outcomes following kidney transplantation. In addition, we provide a primer on the routine listing, evaluation, testing, and candidate selection process in an effort to demystify the current criteria commonly used by transplantation centers. Issues common to a majority of candidates, including cardiovascular health, frailty as a measure of biological age, history of prior malignancy, and high body mass index are reviewed in detail. With this knowledge, we hope to facilitate improved communication between general and transplantation nephrologists.

Keywords: Pre-operative evaluation; age; body mass index (BMI); candidate selection; cardiovascular disease; end-stage kidney disease (ESKD); frailty; kidney transplant; kidney transplant recipient; kidney transplantation; malignancy; nephrologist; obesity; renal replacement therapy (RRT); review; screening; waiting list.

Wall A, Lee GH, Maldonado J, Magnus D. **Medical Contraindications to Transplant Listing in the USA: A Survey of Adult and Pediatric Heart, Kidney, Liver, and Lung Programs.** *World J Surg. 2019 Sep;43(9):2300-2308. doi: 10.1007/s00268-019-05030-x.*

Notes: Survey of US transplant programs (all solid organs) on listing criteria for transplant candidacy.

PMID: 31111229.

Abstract: Introduction: Listing practices for solid organ transplantation are variable across programs in the USA. To better characterize this variability, we performed a survey of psychosocial listing criteria for pediatric and adult heart, lung, liver, and kidney programs in the USA. In this manuscript, we report our results regarding listing practices with respect to obesity, advanced age, and HIV seropositivity.

Methods: We performed an online, forced-choice survey of adult and pediatric heart, kidney, liver, and lung transplant programs in the USA.

Results: Of 650 programs contacted, 343 submitted complete responses (response rate = 52.8%). Most programs have absolute contraindications to listing for BMI > 45 (adult: 67.5%; pediatric: 88.0%) and age > 80 (adult: 55.4%; pediatric: not relevant). Only 29.5% of adult programs and 25.7% of pediatric programs consider HIV seropositivity an absolute contraindication to listing. We found that there is variation in absolute contraindications to listing in adult programs among organ types for BMI > 45 (heart 89.8%, lung 92.3%, liver 49.1%, kidney 71.9%), age > 80 (heart 83.7%, lung 76.9%, liver 68.4%, kidney 29.2%), and HIV seropositivity (heart 30.6%, lung 59.0%, kidney 16.9%, liver 28.1%).

Conclusions: We argue that variability in listing enhances access to transplantation for potential recipients who have the ability to pursue workup at different centers by allowing different programs to have different risk thresholds. Programs should remain independent in listing practices, but because these practices differ, we recommend transparency in listing policies and informing patients of reasons for listing denial and alternative opportunities to seek listing at another program.

Warsame F, Haugen CE, Ying H, Garonzik-Wang JM, Desai NM, Hall RK, Kambhampati R, Crews DC, Purnell TS, Segev DL, McAdams-DeMarco MA. **Limited health literacy and adverse outcomes among kidney transplant candidates.** *Am J Transplant. 2019 Feb;19(2):457-465. doi: 10.1111/ajt.14994. Epub 2018 Aug 16.*

PMID: 29962069.

Abstract: More than one-third of US adults have limited health literacy, putting them at risk of adverse clinical outcomes. We evaluated the prevalence of limited health literacy among 1578 adult kidney transplant (KT) candidates (May 2014-November 2017) and examined its association with listing for transplant and waitlist mortality in this pilot study. Limited health literacy was assessed at KT evaluation by using a standard cutoff score ≤5 on the Brief Health Literacy Screen (score range 0-12, lower scores indicate worse health literacy). We used logistic regression and adjusted Cox proportional hazards models to identify risk factors for limited health literacy and to quantify its association with listing and waitlist mortality. We found that 8.9% of candidates had limited health literacy; risk factors included less than college education (adjusted odds ratio [aOR] = 2.87, 95% confidence interval [CI]:1.86-4.43), frailty (aOR = 1.85, 95% CI:1.22-2.80), comorbidity (Charlson comorbidity index [1-point increase] aOR = 1.12, 95% CI: 1.04-1.20), and cognitive impairment (aOR = 3.45, 95% CI: 2.20-5.41) after adjusting for age, sex, race, and income. Candidates with limited health literacy had a 30% (adjusted hazard ratio = 0.70, 95% CI: 0.54-0.91) decreased likelihood of listing and a 2.42-fold (95% CI: 1.16- to 5.05-fold) increased risk of waitlist mortality. Limited health literacy may be a salient mechanism in access to KT; programs to aid candidates with limited health literacy may improve outcomes and reduce disparities.

Waterman AD, Morgievich M, Cohen DJ, Butt Z, Chakkera HA, Lindower C, Hays RE, Hiller JM, Lentine KL, Matas AJ, Poggio ED, Rees MA, Rodrigue JR, LaPointe Rudow D; American Society of Transplantation. **Living Donor Kidney Transplantation: Improving Education Outside of Transplant Centers about Live Donor Transplantation--Recommendations from a Consensus Conference.** *Clin J Am Soc Nephrol. 2015 Sep 4;10(9):1659-69. doi: 10.2215/CJN.00950115. Epub 2015 Jun 26.*

Notes: Report of consensus conference on best practices for living donor kidney transplantation.

PMID: 26116651.

Abstract: Living donor kidney transplantation (LDKT) offers better quality of life and clinical outcomes, including patient survival, compared with remaining on dialysis or receiving a deceased donor kidney transplant. Although LDKT education within transplant centers for both potential recipients and living donors is very important, outreach and education to kidney patients in settings other than transplant centers and to the general public is also critical to increase access to this highly beneficial treatment. In June 2014, the American Society of Transplantation's Live Donor Community of Practice, with the support of 10 additional sponsors, convened a consensus conference to determine best practices in LDKT, including a workgroup focused on developing a set of recommendations for optimizing outreach and LDKT education outside of transplant centers. Members of this workgroup performed a structured literature review, conducted teleconference meetings, and met in person at the 2-day conference. Their efforts resulted in consensus around the following recommendations. First, preemptive transplantation should be promoted through increased LDKT education by primary care physicians and community nephrologists. Second, dialysis providers should be trained to educate their own patients about LDKT and deceased donor kidney transplantation. Third, partnerships between community organizations, organ procurement organizations, religious organizations, and transplant centers should be fostered to support transplantation. Fourth, use of technology should be improved or expanded to better educate kidney patients and their support networks. Fifth, LDKT education and outreach should be improved for kidney patients in rural areas. Finally, a consensus-driven, evidence-based public message about LDKT should be developed. Discussion of the effect and potential for implementation around each recommendation is featured, particularly regarding reducing racial and socioeconomic disparities in access to LDKT. To accomplish these recommendations, the entire community of professionals and organizations serving kidney patients must work collaboratively toward ensuring accurate, comprehensive, and up-to-date LDKT education for all patients, thereby reducing barriers to LDKT access and increasing LDKT rates.

Waterman AD, Peipert JD, Goalby CJ, Dinkel KM, Xiao H, Lentine KL. **Assessing Transplant Education Practices in Dialysis Centers: Comparing Educator Reported and Medicare Data.** *Clin J Am Soc Nephrol. 2015 Sep 4;10(9):1617-25. doi: 10.2215/CJN.09851014. Epub 2015 Aug 20.*

PMID: 26292696.

Abstract: Background and objectives: The Centers for Medicare & Medicaid Services (CMS) requires that dialysis centers inform new patients of their transplant options and document compliance using the CMS-2728 Medical Evidence Form (Form-2728). This study compared reports of transplant education for new dialysis patients reported to CMS with descriptions from transplant educators (predominantly dialysis nurses and social workers) of their centers' quantity of and specific educational practices. The goal was to determine what specific transplant education occurred and whether provision of transplant education was associated with center-level variation in transplant wait-listing rates.

Design, setting, participants, & measurements: Form-2728 data were drawn for 1558 incident dialysis patients at 170 centers in the Heartland Kidney Network (Iowa, Kansas, Missouri, and Nebraska) in 2009-2011; educators at these centers completed a survey describing their transplant educational practices. Educators' own survey responses were compared with Form-2728 reports for patients at each corresponding center. The association of quantity of transplant education practices used with wait-listing rates across dialysis centers was examined using multivariable negative binomial regression.

Results: According to Form-2728, 77% of patients (n=1203) were informed of their transplant options within 45 days. Educators, who reported low levels of transplant knowledge themselves (six of 12 questions answered correctly), most commonly reported giving oral recommendations to begin transplant evaluation (988 informed patients educated, 81% of centers) and referrals to external transplant education programs (959 informed patients educated, 81% of centers). Only 18% reported having detailed discussions about transplant with their patients. Compared with others, centers that used more than three educational activities (incident rate ratio, 1.36; 95% confidence interval, 1.07 to 1.73) had higher transplant wait-listing rates.

Conclusions: While most educators inform new patients that transplant is an option, dialysis centers with higher wait-listing rates use multiple transplant education strategies.

Waterman AD, Peipert JD, McSorley AM, Goalby CJ, Beaumont JL, Peace L. **Direct Delivery of Kidney Transplant Education to Black and Low-Income Patients Receiving Dialysis: A Randomized Controlled Trial.** *Am J Kidney Dis. 2019 Nov;74(5):640-649. doi: 10.1053/j.ajkd.2019.03.430. Epub 2019 Jun 19.*

PMID: 31227225.

Abstract: Rationale & objective: Compared with others, black and low-income patients receiving dialysis are less likely to receive kidney transplantation (KT) education within dialysis centers. We examined the efficacy of 2 supplementary KT education approaches delivered directly to patients.

Study design: Prospective, 3-arm parallel-group, randomized, controlled trial.

Settings & participants: Adult, black, and white low-income patients receiving dialysis in Missouri.

Intervention: Patients were randomly assigned to 1 of 3 educational conditions: (1) standard of care, usual KT education provided in dialysis centers (control); (2) Explore Transplant @ Home patient-guided, 4 modules of KT education sent directly to patients using print, video, and text messages; and (3) Explore Transplant @ Home educator-guided, the patient-guided intervention plus 4 telephonic discussions with an educator.

Outcomes: Primary: patient knowledge of living (LDKT) and deceased donor KT (DDKT). Secondary: informed decision making, change in attitudes in favor of LDKT and DDKT, and change in the number of new steps taken toward KT.

Results: In intent-to-treat analyses, patients randomly assigned to educator- and patient-guided interventions had greater knowledge gains (1.4 point increase) than control patients (0.8 point increase; P=0.02 and P=0.01, respectively). Compared with control patients, more patients randomly assigned to educator- and patient-guided interventions were able to make informed decisions about starting KT evaluation (82% vs 91% and 95%; P=0.003), pursuing DDKT (70% vs 84% and 84%; P=0.003), and pursuing LDKT (73% vs 91% and 92%; P<0.001).

Limitations: Potential contamination because of patient-level randomization; no assessment of clinical end points.

Conclusions: Education presented directly to dialysis patients, with or without coaching by telephone, increased dialysis patients' KT knowledge and informed decision making without increasing educational burden on providers.

Funding source: This project was funded by the National Institutes of Health and Health Resources and Services Administration.

Trial registration: Registered at ClinicalTrials.gov with study number NCT02268682.

Waterman AD, Peipert JD, Xiao H, Goalby CJ, Kawakita S, Cui Y, Lentine KL. **Education Strategies in Dialysis Centers Associated With Increased Transplant Wait-listing Rates.** *Transplantation. 2020 Feb;104(2):335-342. doi: 10.1097/TP.0000000000002781.*

Notes: Description of transplant education strategies used in dialysis facilities.

PMID: 31335777.

Abstract: Background: Transplant education in dialysis centers can increase access to kidney transplant; however, dialysis center transplant barriers are common, and limited research identifies the most effective transplant education approaches.

Methods: We surveyed transplant educators in 1694 US dialysis centers about their transplant knowledge, use of 12 education practices, and 8 identified education barriers. Transplant wait-listing rates were calculated using US Renal Data System data.

Results: Fifty-two percent of educators orally recommended transplant to patients, 31% had in-center transplant discussions with patients, 17% distributed print educational resources, and 3% used intensive education approaches. Distribution of print education (incident rate ratio: 1.021.151.30) and using >1 intensive education practice (1.001.111.23) within dialysis centers were associated with increased wait-listing rates. Several dialysis center characteristics were associated with reduced odds of using education strategies leading to increased wait-listing. Centers with greater percentages of uninsured patients (odds ratio [OR]: 0.960.970.99), in rural locations (OR: 0.660.790.95), with for-profit ownership (OR: 0.640.770.91), and with more patients older than 65 years (OR: 0.050.110.23) had lower odds of recommending transplant, while centers with a higher patient-to-staff ratio were more likely to do so (OR: 1.011.031.04). Language barriers (OR: 0.480.640.86) and having competing work priorities (OR: 0.400.530.70) reduced the odds of distributing print education. Providers with greater transplant knowledge were more likely to use >1 intensive educational strategy (OR: 1.011.271.60) while providers who reported competing work priorities (OR: 0.510.660.84) and poor communication with transplant centers (OR: 0.580.760.98) were less likely to do so.

Conclusions: Educators should prioritize transplant education strategies shown to be associated with increasing wait-listing rates.

Waterman AD, Peipert JD. **An Explore Transplant Group Randomized Controlled Education Trial to Increase Dialysis Patients' Decision-Making and Pursuit of Transplantation.** *Prog Transplant. 2018 Jun;28(2):174-183. doi: 10.1177/1526924818765815. Epub 2018 Apr 26.*

Notes: Trial of patient educational intervention (Explore Transplant) on knowledge and pursuit of transplantion.

PMID: 29699451.

Abstract: Introduction: Dialysis centers must provide transplant education to patients but often do not address the risks and benefits of living and deceased donor transplant.

Research questions: In a group randomized controlled trial of 20 dialysis centers and 253 patients, we assessed whether the Explore Transplant education program increased patients' readiness to pursue transplant, transplant knowledge, informed transplant decision-making, discussions about transplant with potential living donors, pursuit and receipt of living or deceased donor transplant, and whether these effects varied by race.

Methods: Patients at participating dialysis centers were randomized to receive either (1) a 4-module Explore Transplant education program, including videos, printed materials, and transplant educator discussions or (2) standard-of-care transplant education provided by dialysis centers. The trial had 3 phases: (1) pre- and postsurveying and dialysis center education (2007-2008), (2) follow-up to determine whether patients restarted or began transplant evaluation (2008-2010), and (3) assessment of participants' receipt of a renal transplant (2012-2015).

Results: Compared to patients in standard-of-care dialysis centers, patients who received the intervention were more likely to increase in their stage of readiness for living donor transplantation (odds ratio: 2.50; 95% confidence interval: 1.10-5.66), had greater increases in their transplant knowledge (P < .001), and were more likely to call to restart/begin transplant evaluation (38% vs 24%, P = .006). When analyses were stratified by race, black patients were more likely to take several steps toward transplant in comparison to whites.

Discussion: The Explore Transplant helps dialysis patients make informed decisions and increases their pursuit of transplant, particularly among black patients.

Zhang X, Melanson TA, Plantinga LC, Basu M, Pastan SO, Mohan S, Howard DH, Hockenberry JM, Garber MD, Patzer RE. **Racial/ethnic disparities in waitlisting for deceased donor kidney transplantation 1 year after implementation of the new national kidney allocation system.** *Am J Transplant. 2018 Aug;18(8):1936-1946. doi: 10.1111/ajt.14748. Epub 2018 Apr 18.*

Notes: Study examining impact of the new kidney allocation system on access to transplantation.

PMID: 29603644.

Abstract: The impact of a new national kidney allocation system (KAS) on access to the national deceased-donor waiting list (waitlisting) and racial/ethnic disparities in waitlisting among US end-stage renal disease (ESRD) patients is unknown. We examined waitlisting pre- and post-KAS among incident (N = 1 253 100) and prevalent (N = 1 556 954) ESRD patients from the United States Renal Data System database (2005-2015) using multivariable time-dependent Cox and interrupted time-series models. The adjusted waitlisting rate among incident patients was 9% lower post-KAS (hazard ratio [HR]: 0.91; 95% confidence interval [CI], 0.90-0.93), although preemptive waitlisting increased from 30.2% to 35.1% (P < .0001). The waitlisting decrease is

largely due to a decline in inactively waitlisted patients. Pre-KAS, blacks had a 19% lower waitlisting rate vs whites (HR: 0.81; 95% CI, 0.80-0.82); following KAS, disparity declined to 12% (HR: 0.88; 95% CI, 0.85-0.90). In adjusted time-series analyses of prevalent patients, waitlisting rates declined by 3.45/10 000 per month post-KAS (P < .001), resulting in ≈146 fewer waitlisting events/month. Shorter dialysis vintage was associated with greater decreases in waitlisting post-KAS (P < .001). Racial disparity reduction was due in part to a steeper decline in inactive waitlisting among minorities and a greater proportion of actively waitlisted minority patients. Waitlisting and racial disparity in waitlisting declined post-KAS; however, disparity remains.

Zhou S, Massie AB, Luo X, Ruck JM, Chow EKH, Bowring MG, Bae S, Segev DL, Gentry SE. **Geographic disparity in kidney transplantation under KAS.** *Am J Transplant. 2018 Jun;18(6):1415-1423. doi: 10.1111/ajt.14622. Epub 2018 Jan 27.*

PMID: 29232040.

Abstract: The Kidney Allocation System fundamentally altered kidney allocation, causing a substantial increase in regional and national sharing that we hypothesized might impact geographic disparities. We measured geographic disparity in deceased donor kidney transplant (DDKT) rate under KAS (6/1/2015-12/1/2016), and compared that with pre-KAS (6/1/2013-12/3/2014). We modeled DSA-level DDKT rates with multilevel Poisson regression, adjusting for allocation factors under KAS. Using the model we calculated a novel, improved metric of geographic disparity: the median incidence rate ratio (MIRR) of transplant rate, a measure of DSA-level variation that accounts for patient casemix and is robust to outlier values. Under KAS, MIRR was 1.75 1.811.86 for adults, meaning that similar candidates across different DSAs have a median 1.81-fold difference in DDKT rate. The impact of geography was greater than the impact of factors emphasized by KAS: having an EPTS score ≤20% was associated with a 1.40-fold increase (IRR = 1.35 1.401.45 , P < .01) and a three-year dialysis vintage was associated with a 1.57-fold increase (IRR = 1.56 1.571.59 , P < .001) in transplant rate. For pediatric candidates, MIRR was even more pronounced, at 1.66 1.922.27 . There was no change in geographic disparities with KAS (P = .3). Despite extensive changes to kidney allocation under KAS, geography remains a primary determinant of access to DDKT.

Kidney Disease Quality Measure Development, Maintenance, and Support

Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel Clinical Practice Guidelines

Contents

Environmental Scan Summary

In order to identify existing guidelines and quality measures that may be relevant and applicable to access to transplantation in the ESRD community, UM-KECC performed a preliminary scan of the leading quality measure databases, inventories, and measure development programs.

Key search terms included "kidney transplant", "kidney replacement", "renal transplant", "renal replacement" and "chronic kidney disease". The terms "referral" and "access" were then added to the aforementioned phrases to capture any additional recommendations.

Resources utilized in January 2021 included the National Quality Forum (NQF), the National Quality Measures Clearinghouse (NQMC) and National Guideline Clearinghouse—via the Agency for Healthcare Research and Quality (AHRQ), the National Institute for Health and Care Excellence (NICE), the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI), Kidney Disease Improving Global Outcomes (KDIGO), European Best Practices (EBP), Caring for Australians with Renal Impairment (CARI), and the American Society of Transplantation (AST). Additional guideline recommendations cited in *Clinical Practice Guidelines on Wait-Listing for Kidney Transplantation: Consistent and Equitable?* by Pikli Batabyal et al. were later included from various organizations, including the Canadian Society of Transplantation (CST), the UK Renal Association, the European Association of Urology (EAU), the Transplantation Society of Australia and New Zealand (TSANZ), and the Japanese Society of Nephrology.

The identified guideline recommendations and measures generally fall into three categories relevant to the TEP objectives: 1) those highlighting transplantation as the treatment of choice for most patients requiring renal replacement therapy 2) those emphasizing the importance of discussing renal replacement modality options and potentially referring patients for renal transplant evaluation in a timely manner and 3) those outlining guiding principles for determining candidacy for renal transplantation. From the standpoint of the TEP, the latter may be useful for assessing the potential need for exclusion/inclusion criteria or adjustments in the assessment of access to transplantation, and the first two provide affirmation of the basic importance of developing a measure of access to transplantation.

Clinical Practice Guidelines

KDIGO Clinical Practice Guideline for the Evaluation and Management of Candidates for Kidney Transplantation

Group: Kidney Disease Improving Global Outcomes (KDIGO)
Target population: Adults and children identified with chronic kidney disease (CKD) who are not on renal replacement therapy (RRT) (i.e., not on dialysis or have not received a kidney transplant)
Link: https://kdigo.org/wp-content/uploads/2018/08/KDIGO-Txp-Candidate-GL-Exec-Summary-FINAL.pdf; https://kdigo.org/wp-content/uploads/2018/08/KDIGO-Txp-Candidate-GL-FINAL.pdf
Date: 2020

Strength/Level of Evidence

Grade	Quality of Evidence	Meaning
A	High	The Work Group is confident that the true effect lies close to that of the estimate of the effect.
B	Moderate	The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
C	Low	The true effect may be substantially different from the estimate of the effect.
D	Very Low	The estimate of effect is very uncertain, and often will be far from the truth.

Grade*	Patients	Clinicians	Policy
Level 1: 'The Work Group recommends'	Most people in your situation would want the recommended course of action and only a small proportion would not.	Most patients should receive the recommended course of action.	The recommendation can be evaluated as a candidate for developing a policy or a performance measure.
Level 2: 'The Work Group suggests'	The majority of people in your situation would want the recommended course of action, but many would not.	Different choices will be appropriate for different patients. Each patient needs help to arrive at a management decision consistent with her or his values and preferences.	The recommendation is likely to require debate and involvement of stakeholders before policy can be determined.

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

1.1. The Work Group recommends that all patients with chronic kidney disease (CKD) G4-G5 (glomerular filtration rate [GFR] < 30ml/min/1.73 m2) who are expected to reach end-stage kidney disease [ESKD] (excluding those listed in Rec 1.1.3) be informed of, educated about, and considered for kidney transplantation regardless of socioeconomic status, sex, gender identity, or race/ethnicity **(1D)**.

1.1.1. Refer potential kidney transplant candidates for evaluation at least 6 to 12 months before anticipated dialysis initiation to facilitate identification/work-up of living donors and plan for possible pre-emptive transplantation (Not Graded).

1.1.2. Refer potential candidates already on dialysis when medically stable and kidney failure deemed irreversible **(Not Graded)**.

1.1.3. The Work Group recommends not referring patients for kidney alone transplant evaluation with the following conditions **(1D)**:

- Multiple myeloma, light chain deposition disease or heavy chain deposition disease unless they have received a potentially curative treatment regimen and are in stable remission;
- AL amyloidosis with significant extrarenal involvement;
- Decompensated cirrhosis (consider for combined liver-kidney transplant;
- Severe irreversible obstructive or restrictive lung disease;
- Severe uncorrectable and symptomatic cardiac disease that is deemed by a cardiologist to preclude transplantation;
- Progressive central neurodegenerative disease.

1.1.3.1. Document the reason(s) for not referring patients for transplant evaluation **(Not Graded)**.

1.1.3.2. Inform patients about the reason(s) for not referring for transplant evaluation **(Not Graded)**.

1.1.4. The Work Group recommends delaying transplant evaluation in patients with the following conditions until properly managed **(1D)**:

- An unstable psychiatric disorder that affects decision-making or puts the candidate at an unacceptable level of post-transplant risk;
- Ongoing substance use disorder that affects decision-making or puts the candidate at an unacceptable level of post-transplant risk;
- Ongoing, health-compromising nonadherent behavior despite education and adherence-based counseling;
- Active infection (excluding hepatitis C virus infection) that is not properly treated;
- Active malignancy except for those with indolent and low-grade cancers such as prostate cancer (Gleason score ≤ 6), and incidentally detected renal tumors (≤ 1cm in maximum diameter);
- Active symptomatic cardiac disease (eg, angina, arrhythmia, heart failure, valvular heart disease) that has not been evaluated by a cardiologist;
- Active symptomatic peripheral arterial disease;
- Recent stroke or transient ischemic attack;
- Active symptomatic: peptic ulcer disease, diverticulitis, acute pancreatitis, gallstone/ gallbladder disease, inflammatory bowel disease;
- Acute hepatitis;
- Severe hyperparathyroidism.

1.2. Use a multidisciplinary team, which includes at a minimum a transplant physician, transplant surgeon and a health care professional experienced in the psychosocial aspects of transplantation, to evaluate and decide about suitability for kidney transplantation **(Not Graded)**.

1.3. Approve patients for kidney transplantation that have an estimated survival which is acceptable according to national standards **(Not Graded)**.

1.3.1. Inform patients of their option to seek a second opinion from another transplant center if they are declined **(Not Graded)**.

1.4. The Work Group recommends pre-emptive transplantation with a living kidney donor as the preferred treatment for transplant-eligible CKD patients **(1A)**.

1.4.1. The Work Group recommends pre-emptive transplantation (living or deceased donor) in adults when the estimated glomerular filtration rate (eGFR) is < 10ml/min/1.73 m2 or earlier with symptoms **(1D)**.

1.4.2. The Work Group recommends pre-emptive transplantation (living or deceased donor) in children when the eGFR is < 15ml/min/1.73 m2 or earlier with symptoms **(1D)**.

KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease

Group: Kidney Disease Improving Global Outcomes (KDIGO)

Target population: Adults and children identified with chronic kidney disease (CKD) who are not on renal replacement therapy (RRT) (i.e., not on dialysis or have not received a kidney transplant)

Link: http://www.guideline.gov/content.aspx?id=46510&search=kidney+replacement;
http://www.kdigo.org/clinical_practice_guidelines/pdf/CKD/KDIGO_2012_CKD_GL.pdf

Date: 2012

Strength/Level of Evidence

Grade	Quality of Evidence	Meaning
A	High	The Work Group is confident that the true effect lies close to that of the estimate of the effect.
B	Moderate	The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
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Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

Referral to Specialists and Models of Care

Referral to Specialist Services

- The Work Group recommends referral to specialist kidney care services for people with CKD in the following circumstances (**1B**):
    - AKI or abrupt sustained fall in GFR
    - GFR <30 ml/min/1.73 m^2 (GFR categories G4–G5)*
    - A consistent finding of significant albuminuria (ACR ≥300 mg/g [≥30 mg/mmol] or AER ≥300 mg/24 hours, approximately equivalent to PCR ≥500 mg/g [≥50 mg/mmol] or PER ≥500 mg/24 hours)
    - Progression of CKD (see above for definition)
    - Urinary red cell casts, red blood cells (RBCs) >20 per high power field sustained and not readily explained
    - CKD and hypertension refractory to treatment with 4 or more antihypertensive agents
    - Persistent abnormalities of serum potassium
    - Recurrent or extensive nephrolithiasis
    - Hereditary kidney disease
- The Work Group recommends timely referral for planning renal replacement therapy (RRT) in people with progressive CKD in whom the risk of kidney failure within 1 year is 10% to 20% or higher†, as determined by validated risk prediction tools. (**1B**)

Care of the Patient with Progressive CKD

- The Work Group suggests that people with progressive CKD should be managed in a multidisciplinary care setting. (**2B**)
- The multidisciplinary team should include or have access to dietary counseling, education and counseling about different RRT modalities, transplant options, vascular access surgery, and ethical, psychological, and social care. (**Not Graded**)

Timing the Initiation of RRT

- Living donor preemptive renal transplantation in adults should be considered when the GFR is <20 ml/min/1.73 m^2, and there is evidence of progressive and irreversible CKD over the preceding 6–12 months. (**Not Graded**)

Potential Benefits

- Identification of people at earlier time points in the trajectory of chronic kidney disease (CKD), with appropriate management and earlier referral of those who would benefit from specialist kidney services, should lead to both economic and clinical benefits.

- If CKD is detected early, the associated complications and the progression to kidney failure can be delayed or even prevented through appropriate interventions.

KDOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification

Group: Kidney Disease Outcomes Quality Initiative (KDOQI)
Target population: patients with chronic kidney disease and those at increased risk of chronic kidney disease, except where noted
Link: http://www2.kidney.org/professionals/KDOQI/guidelines_ckd/p1_exec.htm;
Date: 2000

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

Guideline 2: Evaluation and Treatment

The evaluation and treatment of patients with chronic kidney disease requires understanding of separate but related concepts of diagnosis, comorbid conditions, severity of disease, complications of disease, and risks for loss of kidney function and cardiovascular disease.

Patients with chronic kidney disease should be evaluated to determine:

- Diagnosis (type of kidney disease);
- Comorbid conditions;
- Severity, assessed by level of kidney function;
- Complications, related to level of kidney function;
- Risk for loss of kidney function;
- Risk for cardiovascular disease.

Treatment of chronic kidney disease should include:

- Specific therapy, based on diagnosis;
- Evaluation and management of comorbid conditions;
- Slowing the loss of kidney function;
- Prevention and treatment of cardiovascular disease;

- Prevention and treatment of complications of decreased kidney function;
- Preparation for kidney failure and kidney replacement therapy;
- Replacement of kidney function by dialysis and transplantation, if signs and symptoms of uremia are present.

A clinical action plan should be developed for each patient, based on the stage of disease as defined by the KDOQI CKD classification (see table below).

Patients with chronic kidney disease should be referred to a specialist for consultation and co-management if the clinical action plan cannot be prepared, the prescribed evaluation of the patient cannot be carried out, or the recommended treatment cannot be carried out. In general, patients with GFR <30 mL/min/ 1.73 m2 [2] should be referred to a nephrologist.

RPA Guideline recommendations and their rationales for the treatment of adult patients

Group: Renal Physicians Association (RPA)

Target population: Adult patients with acute kidney injury, stage 4 or 5 chronic kidney disease, or end-stage renal disease

Link: http://www.guideline.gov/content.aspx?id=24176

Date: January 2000 (revised October 2010)

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

Informing Patients

Recommendation No 2: Fully Inform AKI, Stage 4 and 5 CKD, and ESRD Patients about Their Diagnosis, Prognosis, and All Treatment Options

In the setting of critical illness many patients with CKD will require urgent dialysis and the vast majority of patients with AKI will have multiple medical problems, in addition to kidney failure. The concept of shared decision making necessitates a multidisciplinary approach including nephrologists, intensivists, and others as appropriate and decisions about acute renal replacement therapy should be made in the context of other life-sustaining treatments. For example, a decision to withhold dialysis in a patient agreeing to and receiving multiple other forms of life sustaining therapy could represent discordant treatment in the same way that offering dialysis to a patient who has decided to forgo other forms of life-sustaining therapy might be inappropriate. Intensive care physicians need to be included in shared decision making for kidney patients in the intensive care unit (ICU).

For ESRD patients, these options in shared decision-making include: 1) available dialysis modalities and kidney transplantation if applicable; 2) not starting dialysis and continuing medical management; 3) a time limited trial of dialysis, and 4) stopping dialysis and receiving end-of-life care. Choices among options should be made by patients or, if patients lack decision-making capacity, their designated legal agents. Their decisions should be informed and voluntary. The renal care team, in conjunction with the primary care physician, should insure that the patient or legal agent understands the benefits and burdens of dialysis and the consequences of not starting or stopping dialysis. Research studies have identified a population of chronic kidney disease patients for whom the prognosis is particularly poor. This population has been found to include patients with two or more of the following characteristics: 1) elderly (defined by research studies identifying poor outcomes in patients who are age 75 years and older); 2) patients with high comorbidity scores (e.g., modified Charlson Comorbidity Index score of 8 or greater); 3) marked functional impairment (e.g., Karnofsky Performance Status Scale score of less than 40); and 4) severe chronic malnutrition (e.g., serum albumin level less than 2.5 g/dL using the bromcresol green method). Patients in this population should be informed that dialysis may not confer a survival advantage or improve functional status over medical management without dialysis and that dialysis entails significant burdens that may detract from their quality of life.

Recommendation No. 10: Use a Systematic Approach to Communicate about Diagnosis, Prognosis, Treatment Options, and Goals of Care

Good communication improves patients' adjustment to illness, increases adherence to treatment, and results in higher patient and family satisfaction with care. Patients appreciate sensitive delivery of information about their prognosis and the ability to balance reality while maintaining hope. In communicating with patients, the critical task for clinicians is to integrate complicated biomedical facts and conditions with emotional, social, and spiritual realities that are equally complex but not well described in the language of medicine. This information must be communicated in a way that patients, legal agents, and families can understand and use to reach informed decisions about dialysis and transplantation options. Patients' decisions should be based on an accurate understanding of their condition and the pros and cons of treatment options. To facilitate effective communication, reliance upon a multidisciplinary approach including nephrologists, intensivists, and others as appropriate is warranted. Decisions about acute renal replacement therapy in AKI should be made in the context of other life-sustaining treatments. Intensive care physicians should be included in shared decision-making for kidney patients in the ICU to facilitate discussions on global disease or injury prognosis. Fellowship programs should incorporate training to help nephrologists develop effective, empathetic communication skills, which are essential in caring for this patient population.

RPA Guideline recommendations and their rationales for the treatment of neonates, infants, children, and adolescents

Group: Renal Physicians Association (RPA)

Target population: Infant, neonatal, children, and adolescent patients with acute kidney injury (AKI), chronic kidney disease (CKD), and end-stage renal disease (ESRD)

Link:
http://www.guideline.gov/content.aspx?id=24177&search=chronic+kidney+disease+and+kidney+and+transplant

Date: October 2010

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

Informing Patients and Parents

Recommendation No. 2: Fully Inform Patients with AKI, Stage 4 or Stage 5 CKD, or ESRD and Their Parents about the Diagnosis, Prognosis, and All Appropriate Treatment Options. Inform Children and Adolescents in a Developmentally Appropriate Manner, and if Feasible, Seek Their Assent about Treatment Decisions

Treatment options include: 1) initiating or continuing dialysis; 2) transplantation for ESRD; 3) not starting dialysis and continuing optimal medical management; and 4) stopping dialysis and continuing to receive palliative treatment. The nephrologist and the medical team should make every effort to inform parents about the potential benefits and burdens of dialysis initiation or dialysis withdrawal before providing or withdrawing treatment. In the rare circumstances when this is not possible, parents should be informed as soon as possible about the rationale for emergent initiation and the efforts that were made to contact the parents before changing the medical plan.

As a component of informed permission/informed assent, and in keeping with the on-going process of both shared decision making and advance care planning, the treating nephrologist may determine that dialysis is no longer providing net benefit (i.e., the risks or burdens outweigh the benefits, the underlying condition is progressive and dialysis is only prolonging the dying process without improving the quality of life during the dying process). In this case, the nephrologist and the medical team should approach the family and discuss the undue burden of dialysis given the patient's medical condition and recommend stopping dialysis and intensifying palliative treatment. This will typically occur in the intensive care setting and intensivists should coordinate the shared decision-making in the context of other aspects of supportive care. Children and adolescents should be given the opportunity to communicate their feelings and perceptions regarding the benefits and burdens of dialysis to the extent they desire to do so and their developmental abilities and health status permits. When seeking informed permission/informed assent for discontinuing dialysis, the medical team should explicitly describe comfort measures and other components of palliative treatment that will be offered.

Facilitating Advance Care Planning

Recommendation No. 5: Institute Family-centered Advance Care Planning for Children and Adolescents with AKI, CKD, and ESRD. The Plan Should Establish Treatment Goals Based on a Child's Medical Condition and Prognosis

Family-centered advance care planning is recommended for infants with poorly functioning or nonfunctioning kidneys due to genetic conditions and those with a non-reversible urological or kidney abnormality. In the event that the health care team has information that the viability of a fetus with suspected multisystem organ involvement is questionable, family-centered advance care planning should occur before the birth of the baby. This will allow the health care team to be able to act decisively in light of the neonate's health status and prognosis at the time of delivery.

Advance care planning should be an ongoing process in which treatment goals are determined and revised based on observed benefits and burdens of dialysis and the values of the pediatric patient and the family. The renal care team should designate a person to be primarily responsible for ensuring that advance care planning is offered to each patient. Patients with decision-making capacity should be *strongly* encouraged to talk to their parents to ensure that they know the patient's wishes and agree to make decisions according to these wishes. Ongoing discussions that include reestablishing goals of care based on the child's response to medical treatment and optimal quality of life is the mechanism by which advance care planning occurs. Discussions should include the pros and cons of dialysis as well as potential morbidity associated with dialysis. Kidney transplantation should also be discussed if appropriate.

Children and adolescents should be allowed to participate in advance care planning commensurate with their preference and developmental status. Parent or pediatric patient questions regarding discontinuation of dialysis if the patient's medical condition becomes irreversible and non-responsive to currently available treatments should be addressed frankly. Such questions can be used as a springboard for obtaining information about parent and child wishes regarding end-of-life care. Assurance should be given that the pediatric patient's comfort is paramount in the event that dialysis is discontinued. In addition, such questions should be used as an opportunity to explicitly describe comfort measures and other components of palliative care.

RPA Clinical Practice Guideline 3: Appropriate Patient Preparation for Renal Replacement Therapy

Group: Renal Physicians Association (RPA)
Target population:
Link: www.renalmd.org/WorkArea/DownloadAsset.aspx?id=974
Date: October 2002

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

Timing Guidelines:

Early Counseling about Modality of RRT

- If a patient has GFR 30 ml/min per 1.73 m2, modality of RRT should be discussed with him/her. (Grade B).

GFR as a Guide to RRT Timing

- No recommendation can be made for initiating RRT based solely on a specific level of GFR. (Grade B).

Early Referral for Transplant Evaluation

- If a patient has GFR 30 ml/min per 1.73 m2 and is willing to have a renal transplant, then s/he should receive a transplant evaluation (Grade B), unless s/he has an unacceptable level of surgical risk or does not satisfy the United Network for Organ Sharing (UNOS) Ethics Committee criteria for transplant candidacy.

AST Clinical Practice Guidelines for the Evaluation of Renal Transplant Candidates

Group: American Society of Transplantation (AST) (Kasiske BL, Cangro CB, et al.)
Target population: Adult or pediatric CKD or ESRD patients
Link: http://onlinelibrary.wiley.com/doi/10.1034/j.1600-6143.2001.0010s2001.x/pdf
Date: 2001

Strength/Level of Evidence

Accordingly, recommendations are graded A, B, C, D, or E when:

A. There is good evidence to support the recommendation that the condition be considered in the evaluation process.
B. There is fair evidence to support the recommendation that the condition be considered in the evaluation process.
C. There is poor evidence regarding the inclusion of the condition in the evaluation process, but recommendations may be made on other grounds.
D. There is fair evidence to support the recommendation that the condition be excluded from consideration in the evaluation process.
E. There is good evidence to support the recommendation that the condition be excluded from consideration in the evaluation process.

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

The timing of renal transplantation
Rationale:
Ideally, renal transplantation should be delayed long enough to maximize the use of the patient’s own kidneys. On the other hand, preemptive transplantation can sometimes allow patients, especially children, to avoid the morbidity and expense of acquiring a dialysis access and initiating dialysis treatments. Preemptive transplantation requires advanced planning and careful attention to the rate of renal disease progression. Early referral to a transplant center is mandatory.

Recommendations:
(C) Candidates should be referred to a transplant center as soon as it appears probable that renal replacement therapy will be needed within the next 6–12 months.

(C) Some candidates who are not yet on dialysis should be considered for preemptive transplantation.

(C) The medical status of patients on the cadaveric transplantation waiting list should be reviewed at least every 2 years. Patients who are diabetic, older than 65, or have a medical condition that could change relatively quickly should be reviewed at least annually.

(C) Candidates should be informed that placement on the cadaveric waiting list does not guarantee transplantation, since changes in their medical status may delay or preclude transplantation.

Donor Source:

Rationale:

Outcomes after renal transplantation are strongly influenced by the choice of the donor. Excellent data are available to advise renal transplant candidates concerning the relative likelihood of successful transplantation from living related, living unrelated (emotionally related) and cadaveric donors.

Recommendations:

(C) Renal transplant candidates should be informed of the risks and benefits (to the donor and/or recipient) and of the risks of using a particular donor, and should be allowed to refuse that donor based on medical grounds.

Cancer:

Most patients treated for cancer benefit from a waiting period prior to renal transplantation. For most patients previously treated for cancer, it appears prudent to recommend a minimum waiting period of 2 years. In the case of some cancers at increased risk for recurrence, a longer waiting interval, e.g. 5 years, should be considered. Some patients with cancers incidentally discovered at the time of evaluation may not require a waiting period prior to renal transplantation.

Rationale:

It is generally accepted that immunosuppression increases the morbidity and mortality of cancer. Effective screening and treatment of cancer prior to transplantation could reduce the risk of posttransplant malignancy. It is prudent to allow sufficient time between the treatment of malignancy and transplantation to exclude patients who will otherwise develop recurrence.

Recommendations:

(A) Patients should be screened for cancer at the time of evaluation and while on the waiting list, following recommendations for the general population.
(B) An appropriate disease-free interval before transplantation should be used to reduce the risk of recurrence (see tables that follow for specific types of cancer).

Infection: Whenever possible, all treatable infections should be eradicated prior to transplantation.

Human immunodeficiency virus (HIV):

Rationale:

There are reasons to believe that outcomes may be either better or worse with renal transplantation and immunosuppression in patients who are HIV antibody positive.

Recommendations:
(A) All renal transplant candidates should be tested for HIVS.
(C) There are insufficient data on which to base a recommendation for or against renal transplantation in patients

Other infection recommendations include:

- Tuberculosis (TB)
- Cytomegalovirus (CMV)
- Dental infections and gingival hyperplasia
- Influenza A and B
- Pneumococcal (Streptococcus pneumoniae) infections
- Childhood infections/immunizations
- Possible screening

Other topics covered include:

- Recurrent Disease
- Gastrointestinal
- Pulmonary
- Cardiovascular disease
- Psychosocial
- Genitourinary
- Endocrine
- Coagulopathies
- Age
- Medications
- Histocompatibility

Steinman-Clinical Practice Committee (AST) Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation

Group: American Society of Transplantation (AST) (Steinman TI, Becker BN, Frost AE, et al.)
Target population:
Link: http://dl2af5jf3e.search.serialssolutions.com/?sid=Entrez:PubMed&id=pmid:11397947
Date: 2001

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

Guideline 1: patient access to referral and consultation at a transplant center.

A. Primary care and/or referring physicians should consider it appropriate to include transplant center referral in their care of patients with organ insufficiency who are ultimately amenable to transplantation.

1. Advantages

a. Kidney transplant candidates may potentially benefit from the possibility of preemptive transplantation.

Guideline 2: indications for referral to or the involvement of a transplant specialist in the care of a patient with organ insufficiency.

A. The patient is a potential organ transplant recipient.

B. Progression towards organ failure has been established.

C. The patient has stated that he or she is willing and interested in transplantation as a possible medical treatment for his or her condition.

D. Discussion about the possibility of living donation can be initiated. Evaluation of the living donor can be processed once the recipient is eligible for transplantation.

Guideline 3. While patients are on the waiting list for transplantation, their primary physician dealing with the organ dysfunction should be advised about necessary follow- up referral at appropriate intervals to the transplant center. Re-evaluation of the patient and advice to the referring physician as to tests required to maintain the patient on the active waiting list are important.

Guideline 4: information management. Primary care providers and the transplant center need to communicate regularly about any changes in the condition of the patient that affect eligibility for transplantation and also maximize quality care for the patient with a complex problem frequently encumbered by co-morbid conditions.

Evaluation of Adult Kidney Transplant Candidates

Group: Suphamai Bunnapradist, MD, and Gabriel M. Danovitch, MD
Target population: Adults with CKD

Link: http://www.ajkd.org/article/S0272-6386%2807%2901147-X/pdf
Date: 2007

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

Kidney transplantation is the treatment of choice for suitable patients with end-stage kidney disease and must be discussed with patients with advanced chronic kidney disease (CKD) preparing for renal replacement therapy. Referral to a transplant program should be performed early to assess candidacy for a preemptive transplantation. One of the main goals of the visit to the transplant center is to educate patients about living and deceased donor transplant options. Potential transplant candidates and their family members should be encouraged to attend formal educational sessions and obtain further information through available literature, including center specific outcomes. Potential transplant recipients also should be familiar with deceased donor organ allocation policy (Table 1).

Evaluation of kidney transplant candidates includes an initial assessment for transplantation suitability. This includes medical, surgical, immunologic, and psychosocial evaluations. The patient's individual risks and benefits of transplantation are discussed so that he or she can make an informed decision about whether to proceed with transplantation. After candidates are placed on the deceased donor list, a periodic reevaluation is necessary to address new issues that may impact on transplant suitability.

WHEN TO REFER

I. Kidney transplantation should be discussed with all patients with irreversible advanced CKD

II. Patients with CKD without known contraindications for transplantation should be referred to a transplant program when they approach CKD stage 4 or a glomerular filtration rate (GFR) less than 30 mL/min/1.73 m2 (_0.5 mL/s/1.73 m2)

III. Early referral will improve the chances of a patient receiving a preemptive transplant, especially those with a potential living donor; referral to a kidney transplant program does not imply immediate transplantation

TRANSPLANTATION WORKUP

Table 2. Contraindications for Kidney Transplantation

Severe uncorrectable systemic conditions with short expected life expectancy

Reversible renal failure

Recent or untreatable malignancy

Uncontrolled psychiatric disorders and active substance abuse

Ongoing noncompliance

Chronic or ongoing active infection

Primary oxalosis (evaluate for combined liver-kidney transplantation)

Limited irreversible rehabilitative potential

Educational Guidance on Patient Referral to Kidney Transplantation

Group: Organ Procurement and Transplant Network (OPTN) Minority Affairs Committee
Target population: All patients with advanced CKD
Link: http://optn.transplant.hrsa.gov/ContentDocuments/Guidance_Kidney_Transplant_Referral.pdf
Date: 2014

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

Purpose
This educational guidance is intended to raise awareness among referring physicians about current trends in the field of kidney transplantation and provide education on identifying patients who are appropriate to be referred for transplant evaluation. The goal of this document is to promote early referral to transplant, explain the barriers to timely referral, and describe the steps patients and providers can take to improve referral patterns.

Kidney Function
All patients with advanced CKD should be considered for transplant evaluation. The medical literature clearly demonstrates that kidney transplant is a superior form of kidney replacement therapy compared to dialysis. As such, referral to transplant should be the default care plan for CKD patients. There are no strict criteria for referral, but most patients with stage 4-5 CKD are appropriate for referral. In select cases, referral at higher levels of kidney function may be appropriate, particularly for patients requiring partial or total nephrectomy or those with rapidly progressive CKD. Early referral provides time for identification and evaluation of potential living kidney donors as well as improved patient education regarding transplant options.

Glomerular Filtration Rate (GFR)
Glomerular filtration rate (GFR) is the measure of kidney function and ranges from 0 to 140 mL/minute with measures ≥ 90 mL/minute considered normal. As GFR may vary from person to person, physician judgment is necessary to appropriately determine the rate of ESRD progression. Since individual patient management will also vary by physician, the GFR measurement should be kept broad with conversations between patients about their CKD status encouraged to be continuous. For example, in patients with a GFR of 30-59 mL/minute (Stage 3 CKD), the referring physician could begin to initiate a conversation about transplantation and prepare the patient for referral if the GFR approaches 30 mL/minute. Referral to transplant evaluation would preferably occur for patients with a GFR of less than 30 mL/minute. Patients progressing toward ESRD at a slower rate may appropriately be referred at a GFR of approximately 25-29 mL/minute but may need to occur at a GFR of 30 mL/minute or above if a patient is rapidly progressing toward ESRD. Physicians are encouraged to refer all medically appropriate patients to transplant once a GFR of less than 30 mL/minute is reached in order to provide sufficient time to

consider and become educated about transplantation, complete a transplant evaluation, and possibly locate a potential living donor.

The goal for referral should be that all potential candidates are referred for transplant at a GFR above 20 to avoid the development of comorbidities associated with dialysis and to allow the patient the maximum waiting time available.

Table 1: Five Stages of Chronic Kidney Disease: GFR Ranges for Referral to Transplant Evaluation

CKD Stage	CKD Description	GFR	Action
1	Kidney Damage with Normal GFR	≤90	Diagnose and Treat Kidney Disease � Slow Progression of Kidney Disease � CVD Risk Reduction
2	Kidney Damage with Mild GFR	60-89	Estimate Progression of Kidney Disease
3	Moderate GFR	30-59	Evaluate and Treat Complications � Initiate discussion about transplantation with all medically appropriate patients, including living donation (GFR 30-35)
4	Severe GFR	15-29	Initiate discussion about transplantation with all medically appropriate patients, including living donation � Recommend transplant education � Refer patients for transplant evaluation.
5	Kidney Failure	<15 or patient on dialysis	Initiate renal replacement therapy � Refer patient for transplant evaluation.

Interest in Transplant

Conventional wisdom has been that patients should express some level of interest in transplantation prior to referral. However, prior to transplant evaluation, many patients have no basis on which to have an opinion about transplant. Expecting interest prior to information may not be a fair basis to decide on referral for evaluation, considering that for every other standard of care therapy patient interest is not a requisite criterion. For example, a patient referred for a heart catheterization is not expected to have knowledge of catheterization risk and benefits and alternatives. Rather, it is expected that the patient will be educated once he sees the cardiologist. Similarly, in transplant, interest necessarily follows information about the survival and quality of life benefits of transplant compared to dialysis. Interest in transplantation should be appropriately gauged after transplant education has been provided and should not be part of the decision to refer for kidney transplant evaluation.

Comorbid Conditions

Kidney transplant candidates often have comorbid conditions in addition to ESRD. Advances in pre- and post-transplant care have made transplantation an option for patients with significant comorbid conditions including coronary artery disease, peripheral vascular disease, chronic obstructive pulmonary disease, and chronic liver disease. Assessment of the impact of concomitant illness on perioperative and post-transplant morbidity and mortality is often the primary focus of the transplant evaluation, and the process often requires input from consulting services. Exclusion criteria based upon medical conditions vary significantly between programs. These criteria are often quite broad and listing decisions are often based on close review of each specific patient’s conditions. While such patients with severe comorbid illness may not qualify for a kidney transplant alone, they may be candidates for combined transplants such as heart-kidney or liver-kidney. Ideally, most patients should be allowed the opportunity to be evaluated for a transplant. The existence of comorbid conditions should not preclude referral for transplant evaluation.

Transplant Evaluation

During a typical transplant evaluation, the patient will meet with a transplant nephrologist, transplant surgeon, transplant coordinator, social worker, psychologist and potentially also a financial coordinator, pharmacist, and dietician. Testing typically includes cardiac testing (EKG, Echo, stress test, and may include cardiac catheterization, if deemed necessary), chest X-rays, blood tests, routine health screenings (PAP/mammogram for women; colonoscopy for patients over age 50), and a dental examination. Additional testing may be needed based on the patient's medical history.

Timely referral of patients for transplant evaluation allows the patient an opportunity to learn more about the processes of transplantation including the evaluation, waitlisting, and post-transplant protocols. The patients may be overwhelmed at first with the volume of information presented, which is why it is essential for patients to be seen early to be able to receive the necessary information and understand their options.

Most transplant centers provide patients with easy-to-read brochures explaining the process of evaluation and waitlisting. This allows the patient the opportunity to learn about the kidney transplant surgery and to find out what to expect after transplant at a more leisurely pace. Transplant centers are also making a concerted effort to ensure that the referring providers are kept abreast of their patient's progress through the evaluation process.

Barriers to Transplantation

Although transplantation is considered to be the optimal therapy for ESRD, many factors pose as barriers to transplantation for patients who could receive benefit.[23] The most significant barriers identified in the literature are identified and discussed below:

1. Timing of referral
2. Medical insurance
3. Financial issues and transportation
4. Availability of living kidney donors
5. Patient education and understanding of ESRD/transplantation
6. Provider understanding of the waitlisting and transplantation process
7. Other barriers

Timing of Referral

The ideal approach to the problem of CKD and ESRD is prevention through education and lifestyle changes. However, patients with progressive CKD should be proactively directed towards kidney transplantation. Multiple studies have shown that, compared to dialysis, kidney transplantation offers superior quality of life and improvement in patient survival.[2, 3] In this light, the default pathway for patients with advanced CKD should be transplantation. However, in current practice, physicians see that transplant options are not presented to patients in a timely manner.

Transplant Education

Clinicians are encouraged to work with local transplant centers to advocate for providing transplant education to patients. There is currently a precedent for provision of transplant education which may be reimbursed through the federal government. Providers are incentivized to provide transplant education to patients with chronic kidney disease, which is billed separately through specific coding/billing mechanisms.

The education can be provided by physicians and non-physician providers (nurse practitioners, clinical nurse specialists, and physician assistants) and hospital-based dialysis providers in rural areas only. Outpatient dialysis facilities may not provide this service.

Perhaps the most significant barrier to preemptive kidney transplantation is timely referral for transplant evaluation. Currently, the majority of patients referred for kidney transplant evaluations are already on dialysis. Part of the consequence of these late referrals is that only 14.4% of adult kidney transplants performed in 2011 were preemptive.[25] Late referral is not a sensible approach to maximize patient outcomes when one has a good understanding of the kidney transplant allocation system. Currently, an evaluated and medically and psychosocially approved patient can be placed on the waiting list and accrue waiting time at the time the estimated glomerular filtration rate (eGFR) or equivalent measure is less than or equal to 20 mL/minute.[26] As such, providers should strive to have a patient evaluated and approved so that as soon as the eGFR is 20 mL/minute the patient can be activated on the waiting list. The importance of early referral is two-fold. Given that patients typically initiate dialysis at a GFR of 10-15 mL/minute, early referral allows the patient to accumulate some and ideally all of their waiting time prior to initiation of dialysis. [26] Second, early referral allows the patient more time to look for potential living donor candidates, enhancing the chances that they will obtain a preemptive live donor transplant. Providers should also consider that many patients presenting for kidney transplant evaluation have multiple medical comorbidities and, as a result, may require multiple tests and procedures prior to being deemed medically acceptable for transplantation. This work-up can take months to complete, so early referral allows the patient to accrue the maximum amount of waiting time possible.

Canadian Society of Transplantation consensus guidelines on eligibility for kidney transplantation

Group: Canadian Society of Transplantation (CST)
Target population: Canadian patients with ESRD
Link: http://www.cmaj.ca/content/173/10/S1.full.pdf
Date: 2005

Strength/Level of Evidence

Grade A — There is good evidence to support
Grade B — There is fair evidence to support
Grade C — The existing evidence is conflicting, but other factors may influence decision-making
Grade D — There is fair evidence to recommend against

Grade E — There is good evidence to recommend against

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

1. All patients with end-stage renal disease should be considered for kidney transplantation provided no absolute contraindications exist (Grade A).

2. Eligibility for kidney transplantation should be determined on medical and surgical grounds. Criteria for eligibility should be transparent and made available to patients and the public. Eligibility should not be based on social status, gender, race or personal or public appeal (Grade C).

3. A patient declined for transplantation should routinely be offered a second opinion from an alternative physician or surgeon or a committee able to assess the relative risks and benefits of kidney transplantation (Grade C).

Timing of referral

1. Potential transplant recipients should be referred for evaluation by a transplant program once renal replacement therapy is expected to be required within the next 12 months (Grade C).

2. Patients already requiring dialysis support should be referred for transplant evaluation as soon as their medical condition stabilizes (Grade C).

Renal function

1. Preemptive kidney transplantation is the preferred form of renal replacement therapy and should be encouraged where feasible (Grade A).

2. Preemptive kidney transplantation should not proceed unless the measured or calculated glomerular filtration rate is < 20 mL/minute and there is evidence of progressive and irreversible deterioration in renal function over the previous 6–12 months. Exceptions may be made for patients receiving combined organ transplants where a kidney transplant is combined with a non-renal organ. However, the appropriate policy on this issue is not clear at this time (Grade C).

Other evaluation considerations discussed in the guidelines for transplantation include:

- Age and functional capacity
- Obesity
- Cause of end-stage renal disease
- Systemic diseases
- Infections
- Malignancy
- Pulmonary disease
- Cardiac disease

- Cerebral vascular disease
- Peripheral vascular disease
- Gastrointestinal disease
- Liver disease
- Genitourinary disease
- Hematologic disorders
- Hyperparathyroidism
- Psychosocial considerations

Early identification and management of chronic kidney disease in adults in primary and secondary care

Group: National Clinical Guideline Centre/ National Institute for Health and Clinical Excellence (NICE)

Target population: Adults aged 18 and over who have or are at risk of developing chronic kidney disease (CKD), with specific consideration given to the needs of subgroups:

- Older people (75 years and older)
- Black and minority ethnic people where these differ from the needs of the general population
- People at high risk of developing CKD (for example, people with: diabetes, hypertension, cardiovascular disease, or people recovering from acute kidney injury)

Link: http://www.guideline.gov/content.aspx?id=48405&search=kidney+transplantation+guidelines

Date: 2008 Sep (revised 2014 Jul)

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

Information and Education

Offer people with CKD education and information tailored to the severity and cause of CKD, the associated complications and the risk of progression. **[2008]**

When developing information or education programs, involve people with CKD in their development from the outset. The following topics are suggested.

- What is CKD and how does it affect people?
- What questions should people ask about their kidneys?
- What treatments are available for CKD, what are their advantages and disadvantages and what complications or side effects may occur as a result of treatment/medication?
- What can people do to manage and influence their own condition?
- In what ways could CKD and its treatment affect people's daily life, social activities, work opportunities and financial situation, including benefits and allowances available?
- How can people cope with and adjust to CKD and what sources of psychological support are available?

- When appropriate, offer information about renal replacement therapy (such as the frequency and length of time of dialysis treatment sessions or exchanges and preemptive transplantation) and the preparation required (such as having a fistula or peritoneal catheter).
- Conservative management and when it may be considered. **[2008]**

Offer people with CKD high-quality information or education programs as appropriate to the severity of their condition to allow time for them to fully understand and make informed choices about their treatment. **[2008]**

Healthcare professionals providing information and education programs should ensure they have specialist knowledge about CKD and the necessary skills to facilitate learning. **[2008]**

Healthcare professionals working with people with CKD should take account of the psychological aspects of coping with the condition and offer access to appropriate support – for example, support groups, counselling or a specialist nurse. **[2008]**

Referral Criteria

Take into account the individual's wishes and comorbidities when considering referral. **[2008]**

People with CKD in the following groups should normally be referred for specialist assessment:

- GFR less than 30 ml/min/1.73 m^2 (GFR category G4 or G5), with or without diabetes
- ACR 70 mg/mmol or more, unless known to be caused by diabetes and already appropriately treated
- ACR 30 mg/mmol or more (ACR category A3), together with haematuria
- Sustained decrease in GFR of 25% or more, and a change in GFR category or sustained decrease in GFR of 15 ml/min/1.73 m^2 or more within 12 months
- Hypertension that remains poorly controlled despite the use of at least 4 antihypertensive drugs at therapeutic doses (see also the NGC summary of the NICE guideline Hypertension. Clinical management of primary hypertension in adults [NICE clinical guideline 127])
- Known or suspected rare or genetic causes of CKD
- Suspected renal artery stenosis. **[2008, amended 2014]**

UK Renal Association Clinical Practice Guidelines for the Assessment of the Potential Kidney Transplant Recipient

Group: UK Renal Association

Target population: Patient with chronic kidney disease stage 5

Link: http://www.european-renal-best-practice.org/content/guidelines-topic-transplantation; http://www.renal.org/guidelines/modules/assessment-of-the-potential-kidney-transplant-recipient#sthash.U06sP0rP.dpbs

Date: 2010 (final version 2011)

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

Guideline 1. Access to renal transplantation (Tx) (Guidelines Tx 1.1 – 1.9)

Guideline 1.1

We recommend that kidney transplantation should be the renal replacement therapy of choice for the patient with chronic kidney disease stage 5 who is considered fit for major surgery and for chronic immunosuppression. All patients predicted to have an increased life expectancy post-transplantation should be assessed for transplantation. Placement on the transplant waiting list will be limited by individual co-morbidity and prognosis.

Guideline 1.2

We recommend that living donor transplantation should be considered the treatment of choice for all patients suitable for renal transplantation when there is an appropriate donor.

Guideline 1.3

We recommend that patients with progressive deterioration in renal function suitable for transplantation should be placed on the national transplant list within six months of their anticipated dialysis start date. Pre-emptive transplantation should be the treatment of choice for all suitable patients whenever a living donor is available.

Guideline 1.4

We recommend that there must be demonstrable equity of access to deceased donor kidney transplantation irrespective of gender, ethnicity or district of residence.

Guideline 1.5

We recommend that age is not a contra-indication to transplantation but age related co-morbidity is an important limiting factor.

Guideline 1.6

We recommend that all transplant units should have written criteria for acceptance on to the waiting list. The benefits and potential risks associated with transplantation should be fully explained both verbally and in writing. Potential transplant recipients should be informed of all donor options including living related and unrelated donation and the NHSBT/BTS guidelines for consent for solid organ donation should be followed.

Guideline 1.7

We recommend that all CKD 5 patients and CKD 4 patients with progressive disease should have their suitability for transplantation assessed annually and that appropriate patients should be referred to a transplant center. When transplantation is considered inappropriate the reason(s) should be documented. All patients on the transplant list should be assessed annually to determine whether transplantation remains appropriate. Patients should be placed on, or removed from the waiting list only after discussion and agreement with the nephrologist, transplant surgeon and the patients themselves according to local practice.

Guideline 1.8
We recommend that the care of the renal transplant recipient is best undertaken by a multi-disciplinary team.

Guideline 1.9
We recommend that simultaneous kidney-pancreas transplantation or living donor renal transplantation is the treatment of choice for patients with Type 1 diabetes mellitus who are suitable for renal transplantation.

Guideline 2. Evaluation, selection and preparation of the potential transplant recipient (Tx) (Guidelines Tx 2.1 – 2.9)

Guideline 2.1 – Tx : Pre-transplant assessment
We recommend that the object of pre-transplant assessment is: a) to ensure transplantation is technically possible; b) to ensure the recipient’s chances of survival are not compromised by transplantation; c) to ensure that graft survival is not limited by premature death (maximum benefit obtained from a limited resource); d) to ensure pre-existing conditions are not exacerbated by transplantation; e) to identify measures to be taken to minimize peri- and post-operative complications; f) to inform patients of the likely risks and benefits of transplantation.

Guideline 2.2 – Tx : Pre-transplant cardiac assessment
We suggest that there is no compelling evidence that pre-transplantation screening tests for coronary artery disease in asymptomatic patients with established renal failure is effective in preventing future cardiac events or reducing mortality after transplantation.

Until better evidence emerges, screening tests may be best used to identify high-risk patients for exclusion from the transplant waiting list.

Guideline 2.3 – Tx : Preparation of the renal transplant recipient
We suggest that the use of pre-operative beta-blockers may be considered in patients at high cardiovascular risk undergoing renal transplantation but should be introduced at least 1 month before transplantation. Beta-blockers should not be discontinued abruptly peri-operatively. Low dose aspirin and clopidogrel therapy are not contraindications to transplantation.

Guideline 2.4 – Tx : Preparation of the renal transplant recipient
We recommend that patients should be strongly encouraged to stop smoking before and after transplantation. Formal smoking cessation programs should be offered and accessed in primary care.

Guideline 2.5 – Tx : Preparation of the renal transplant recipient
We suggest that obese patients (BMI >30 kg/m2) present technical difficulties and are at increased risk of peri-operative complications. They should be screened rigorously for cardiovascular disease and each case considered individually. Although obesity is not an absolute contra-indication to transplantation, individuals with a BMI >40 kg/m2 are less likely to benefit.

Guideline 2.6 – Tx : Preparation of the renal transplant recipient
We recommend that all potential transplant recipients should be tested for prior exposure to viral infections including: cytomegalovirus (CMV), Epstein-Barr virus (EBV), varicella zoster virus (VZV), hepatitis B and C and human immunodeficiency virus (HIV). Immunization should be offered to all

hepatitis B (if not already immunized) and VZ virus antibody negative patients before transplantation. Patients otherwise suitable for renal transplantation with evidence of chronic hepatitis B and/or C or HIV infection should be managed according to British Transplantation Society and European Best Practice Guidelines prior to transplantation.

Guideline 2.7 – Tx : Evaluation and selection of the renal transplant recipient
We recommend that renal transplantation should only be considered in potential recipients with previous malignancy (excluding non-melanoma skin cancer) if there is no evidence of persistent cancer. It is recommended that the waiting time between successful tumor treatment/remission and transplantation be at least 2 years. For certain malignancies the waiting time may need to be extended to more than 5 years. The Israel Penn International Transplant Tumor Registry should be consulted for tumor specific advice (www.ipittr.uc.edu/Home.cfm).

Guideline 2.8 – Tx : Evaluation and selection of the renal transplant recipient
We recommend that patients who are at risk of developing recurrence of original renal disease should be managed according to the European Best Practice Guidelines (EBPG).

Guideline 2.9 – Tx : Screening investigations in the renal transplant recipient
We suggest that there is no evidence that asymptomatic potential transplant recipients require screening for diverticular disease, peptic ulceration or gall bladder stones.

Summary of audit measures in assessment for renal transplantation

- The proportion of patients with and without diabetes mellitus < 65 years old with CKD stage 5 listed for transplantation.
- The proportion of transplant patients who receive a living donor transplant.
- The time to placement on the UK Transplant national transplant list in relation to start date of dialysis.
- The proportion of living donor transplant recipients transplanted before starting dialysis.
- A comparison between renal units of the proportion of dialysis patients placed on the national transplant list corrected for differences in identified unit and patient specific variables including co-morbidity.
- The proportion of CKD stage 5 patients with a transplant status recorded.
- The proportion of CKD stage 5 dialysis patients with Type 1 diabetes mellitus listed for simultaneous kidney-pancreas transplantation.
- The proportion of patients who smoke (or have given up within the last year)
  a. whilst listed for transplantation

  b. one year after renal transplantation.
- The number of patients with BMI >40 kg/m2 who are on the transplant waiting list and the reason for their inclusion.
- The proportion of patients on the transplant waiting list whose viral status is known for CMV, EBV, VZV, hepatitis B and C and HIV.
- The proportion of VZV and HBc antibody negative patients on the transplant.

EAU Guidelines on Renal Transplantation

Group: European Association of Urology (EAU)
Target population: European patients with CKD or ESRD
Link: http://www.uroweb.org/gls/pdf/Renal%20Transplantation%202010.pdf
Date: 2005 (updated 2009)

Strength/Level of Evidence

Grade:	Nature of Recommendations
A	Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomized trial
B	Based on well-conducted clinical studies, but without randomized clinical trials
C	Made despite the absence of directly applicable clinical studies of good quality

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

- Active infection, which may exacerbate after transplantation causing life-threatening infection, is a contraindication to transplantation (B)

- Carry out screening for viral and bacterial diseases in all transplant candidates; Screen all patients for HBV, HCV, HIV and CMV and TB (history and chest X-ray) (B)

- Routine screening examination of all patients in all subspecialties is not necessary (B)

- In severe co-morbidity or non-compliance, a thorough and individual assessment should be performed (C)

- Pre-transplant work-up should focus on the presence of cardiac disease (B)

- In patients with a high risk of cardiac disease, an extensive work-up is strongly recommended to firmly rule out coronary artery disease (B)

- Perform any revascularization before transplantation (B)

- During pre-transplant work-up, special attention should be paid to iliacal, peripheral and cerebrovascular disease. Appropriate diagnostic and therapeutic measures are recommended (C)

- Patients with diabetes mellitus should be transplanted. They require an extensive pre-transplant work-up (B)

• Obesity itself is not a contraindication for transplantation. However, a thorough pre-transplant evaluation and attempt to reduce weight are recommended (C)

• A careful examination of coagulopathies in patients at risk in order to prevent early post-transplant thrombotic events is recommended (C)

• Pre-transplant work-up for patients with retransplantation or previous non-renal transplantation should focus on the immunological risk, including a thorough analysis for the presence of anti-HLA antibodies

European Best Practice Guidelines for Renal Transplantation (Part 1)

Group: ERBP (European Renal Best Practice)
Target population: All patients with end-stage renal disease (ESRD) with exception of absolute contra-indications
Link: http://www.european-renal-best-practice.org/content/ebpg-european-best-practice-guidelines-documents; http://ndt.oxfordjournals.org/content/15/suppl_7
Date: December 2, 2000

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

I.1 Epidemiological data concerning end-stage renal failure (ESRF) and its treatment in Europe Guideline

- In estimating the number of patients in need of renal transplantation, one should integrate the basic epidemiological data concerning end-stage renal failure (ESRF), and in particular the currently linear increase of the point prevalence by ~7.5% each year.

I.2 General evaluation guidelines

- All patients with end-stage renal disease (ESRD) should be considered for renal transplantation unless they have absolute contra-indications, because renal transplantation offers a better life expectancy and quality of life than dialysis.
- Long duration of dialysis, previous incidence of recurrent infections, cancer, cardiovascular disease or gastrointestinal complications should not be considered as absolute contra-indications to renal transplantation, despite these conditions increasing the risk of post-transplant morbidity and mortality.
- Psychological evaluation of transplant candidates may be useful in assessing compliance with future immunosuppressive treatment. Poor compliance significantly worsens the outcome of renal allografts.

I.3 Information for the transplant recipient guidelines

- Comprehensive information on renal transplantation should be given to all potential candidates with ESRF, including mortality, morbidity, results compared with dialysis, and also data concerning the different sources of kidneys, including marginal organs.
- The specific transplant evaluation should only be performed after this information is delivered and clear acceptance is given by the patient. Inclusion on the waiting list is the final step of the procedure and requires formal information consent (often legal) from the prospective recipient.
- All critical aspects concerning kidney donor selection for transplantation, including the use of marginal organs, need clear informed consent from the prospective candidate, both in advance, whenever possible, and at the time of an offer.

I.4 Contra-indications for transplant guideline

- There are a few absolute contra-indications to renal transplantation. These include uncontrolled cancer, HIV positivity, active systemic infections and/or any condition with a life expectance < 2 years.

I.5 Risk factors / relative contra-indications

I.5.1 Work-up for cancer and waiting time for pre-existing cancer guidelines

- Candidates for renal transplantation, particularly those older than 50 years of age, should be screened for the presence of pre-existing cancer.
- Inpatients with previous cancer, renal transplantation should only be considered if there is no evidence of persistent cancer. It is recommended that the waiting time between tumor treatment and transplantation be based on the type of cancer.
- After renal transplant, general preventive measures of surveillance for occurrence of *de novo* cancer are recommended.

I.5.2 Infection risk. Hepatitis C virus (HCV) infection in kidney transplant recipients and kidney donors guidelines

- All transplant candidates should be tested for anti-HCV antibodies. Anti-HCV positive patients with negative HCV viraemia are at very low risk of liver disease after renal transplantation. The presence of HCV_RNA in serum maybe searched for in all prospective recipients with liver disease, even in cased where anti-HCV antibodies are not detectable.
- All HCV-positive patients should be considered for renal transplantation, as this procedure is not associated with increased mortality compared with dialysis, at least not during the first post-transplant decade.
- HCV-infected transplant candidates with elevated transaminase levels should undergo a liver biopsy. It is desirable, but not essential, to perform a liver biopsy in HCV-infected patients who display consistently normal liver enzymes, because HCV liver disease is often undetected.
- Transplant candidates with existing cirrhosis should not be considered for isolated renal transplantation, but should be considered for combined kidney and liver graft.
- Patients with chronic active hepatitis (CAH) might be offered a treatment with interferon (IFN-α) prior to transplantation. They may be maintained on the active transplant waiting list during the

period of IFN-α administration, the drug being stopped if transplantation occurs before the end of planned therapy. Patients without improvement after IFN-α therapy may still be put on the waiting list for transplantation, but only after careful consideration and information.

- Kidneys from HCV-infected living or cadaveric donors may be offered to HCV RNA-positive recipients with their consent and when permitted by the national law. Obtaining the donor and recipient HCV genotypes is desirable for further careful evaluation of the results.

KHA-CARI Guideline: Recipient Assessment for Transplantation

Group: Kidney Health Australia – Caring for Australasians with Renal Impairment (KHA-CARI)

Target population: All kidney transplant candidates

Link:
http://www.cari.org.au/Transplantation/transplantation%20recipient%20assessment/transplant_recipient_assessment.html;
http://www.cari.org.au/Transplantation/transplantation%20recipient%20assessment/Summaries/Campbell_2013_455.pdf

Date: 2013

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

1. Cardiovascular disease guideline recommendations

- We recommend that all candidates for kidney transplant are screened for cardiovascular risk factors.
- We suggest that kidney transplant candidates with a low clinical risk of cardiovascular disease do not require stress testing for coronary artery disease.
- We suggest that kidney transplant candidates with a moderate or high clinical risk of cardiovascular disease undergo cardiac stress testing prior to transplantation.
- We recommend that coronary angiography be considered for kidney transplant candidates with abnormalities on screening procedures.
- We suggest that the benefit of revascularization prior to transplantation be reviewed on an individual basis.

2. Diabetes mellitus guideline recommendations

- We recommend that diabetes should not on its own preclude a patient from being considered for kidney transplantation.
- We recommend that potential renal transplant candidates with diabetes are screened for cardiovascular disease in accordance with the 'Cardiovascular Disease' sub-topic guidelines.
- We suggest that renal transplant candidates with diabetes be considered for pre-emptive transplantation due to better patient and graft survival compared with transplantation after the commencement of dialysis.

- We suggest that, following screening for cardiovascular disease, Type 1 diabetic transplant candidates should be considered for referral for simultaneous pancreas and kidney transplantation (SPK) or live donor renal transplantation.

3. Human immunodeficiency virus, hepatitis b virus, hepatitis c virus guideline recommendations

- Human Immunodeficiency Virus (HIV)
  We recommend that HIV infection should not preclude a patient from being assessed for kidney transplantation.

- Hepatitis B Virus (HBV)
  We recommend that HBV infection should not preclude a patient from being assessed for kidney transplantation.

- Hepatitis C Virus (HCV)
  We recommend that HCV infection should not preclude a patient from being assessed for kidney transplantation.

4. Malignancy guideline recommendations

- We recommend that screening for malignancy prior to transplantation be conducted in accordance with usual age and sex appropriate cancer screening policies for the general population.
- We recommend that patients with the following malignancy not be transplanted:

  i. Uncontrolled or untreated malignancies
  ii. Multiple myeloma
  iii. Advanced breast cancer (stage III)
  iv. Colorectal cancer (stage D)
- We suggest minimum waiting periods from successful treatment of malignancy to transplantation.
- We suggest advising patients with a prior malignancy that they are at increased risk of de novo malignancy post-transplantation compared with those with no prior history of malignancy undergoing transplantation.

5. Obesity guideline recommendations

- We recommend that obesity should not on its own preclude a patient from being considered for kidney transplantation.
- As a pre transplant BMI (Body Mass Index) >40 kg/m2 may not be associated with a survival advantage compared to remaining on dialysis, we suggest that the suitability for transplant be carefully assessed on an individual basis.
- As patient and graft survival of obese transplant recipients may be mediated by comorbid factors, particularly cardiovascular, we recommend that obese transplant candidates are

screened for cardiovascular disease (refer to 'Cardiovascular Disease' sub-topic guidelines for recommendations).

6. Pediatric recipient guideline recommendations

- In relation to age at the time of transplantation, we recommend that:
    - There be no lower age limit set for transplantation.
    - In infants under 1 year of age, transplantation should be performed in highly specialized units with extensive experience in pediatric transplantation.
    - In infants under 1 year of age, adult live donors should be used in preference to cadaveric donors.
- In all patients but particularly in adolescents we recommend that:
    - Risk factors for non-adherence are identified prior to transplantation.
    - Specific strategies are implemented to actively manage factors and behaviors that contribute to non-adherence.
- We recommend that children with urological abnormalities be carefully assessed prior to transplantation and that abnormalities in bladder emptying are corrected before transplantation.
- We suggest that asymptomatic vesicouretic reflux does not require correction prior to transplantation.
- We suggest that children with Wilms tumor wait at least 2 years following completion of chemotherapy before undergoing transplantation.
- We suggest that post-transplant anticoagulation be considered for children with thrombophilic disorders.
- We recommend that mental retardation should not preclude an individual from consideration for transplantation.

TSANZ Consensus statement on eligibility criteria and allocation protocols

Group: The Transplantation Society of Australia and New Zealand (TSANZ)
Target population:
Link: http://www.tsanz.com.au/downloads/concensusstatementv1.38jan2014_000.pdf
Date: 2014

Major Recommendations

3.1 Inclusion criteria

Inclusion criteria for kidney transplantation are: end-stage kidney failure requiring dialysis; anticipated low perioperative mortality; and a reasonable postoperative life expectancy, defined as an 80% likelihood of surviving for at least 5 years after transplantation.

3.2 Exclusion criteria

Exclusion criteria for kidney transplantation are as follows.

An anticipated likelihood of less than 80% chance of surviving a minimum of 5 years following transplantation — comorbidities that might have a significant impact on the life expectancy of a kidney transplant recipient include cardiac disease, vascular disease, diabetes mellitus and malignancies.

Cardiovascular disease — Substantial, uncorrectable cardiovascular disease would be an absolute exclusion. Lesser levels of disease would potentially contribute to a lower anticipated 5-year survival, and hence would be a relative consideration.

Diabetes mellitus – Uncomplicated diabetes mellitus is not a contra-indication to transplantation. The presence of diabetes should lead to detailed assessment of potential vascular complications that would potentially contribute to a lower anticipated 5-year survival, and hence would be a relative consideration.

Infection — Uncontrolled infection is a contraindication to transplantation.

Malignancy — Active malignancies other than non-melanoma skin cancers remain an absolute contraindication to kidney transplantation, however patients with ‘cured’ malignancy as evidenced by prolonged disease-free survival may be suitable for transplantation. A decision on whether or not to refer patients with a history of malignancy for kidney transplant assessment needs to be individualized and generally should only be made in consultation with the oncologist caring for the patient.

Inability to comply with complex medical therapy — The ability to correctly follow a treatment plan, particularly with respect to anti-rejection medications is an important predictor of a successful outcome after renal transplantation, and as such is a requirement for renal transplant listing. Every effort should be made to assist patients and their carers to optimize their adherence to therapy.

Other medical conditions — Patients with renal failure can have any number of comorbid medical conditions that can affect the chances of a successful outcome. Others include cardiac failure, chronic airways disease, cirrhosis of the liver, peripheral vascular disease and cerebrovascular disease. The impact of these conditions needs to be considered on a case-by-case basis.

Age — Although advanced age in the absence of significant medical comorbidity is not necessarily a contraindication for kidney transplantation, fewer than 5% of the end-stage kidney failure patients in Australia aged over 65 are currently listed for renal transplantation due to the presence of comorbidities.7

Similar survival outcomes should be expected for recipients receiving combined transplants, where a kidney is transplanted with another organ (liver, pancreas, heart, and lung).

Patients who are being considered for a second or subsequent kidney transplant should be assessed according to the same requirements as candidates for their first kidney transplant.

3.3 Assessment and acceptance principles

Referrals for renal transplantation (from renal/dialysis units) should be assessed initially at the level of the transplanting hospital. This review and a decision regarding acceptance for listing should involve a transplant physician and surgeon.

The transplant unit should have a system to allow borderline candidates to be assessed by a broader group of transplant specialists.

Each state should have a second-tier review committee (the structure of which may vary between states) to review cases where requested.

Reassessment of patients on the waiting list should occur at least annually by the transplant unit. Usually this would be in person. Transplant units will have a process to formally ensure ongoing suitability.

Only the Director of a transplant unit (or their delegate) has the authority to have patients added to the active renal transplant waiting list.

Japanese Society of Nephrology Evidence-based practice guideline for the treatment of CKD

Group: Japanese Society of Nephrology
Target population: Japanese patients with CKD
Link: http://www.jsn.or.jp/en/guideline/pdf/guideline2009.pdf
Date: 2009

Major Recommendations

The following text is an abridged version of the guideline recommendations; please refer to the full report for additional information.

1. Kidney transplantation as a treatment option for end stage kidney disease (Grade A, Level 4)
Since kidney transplantation generally confers a survival benefit, this treatment option for end-stage kidney disease should be explained to all patients with CKD stage 4 and 5, and also to their family [1].

2. Significance of pre-emptive kidney transplantation (Grade B, Level 4)
Living donor kidney transplantation can be performed prior to the initiation of dialysis, which is called ‘‘preemptive kidney transplantation (PET)’’. PET is reported to be superior in terms of patient and graft survival compared to kidney transplantation after the initiation of dialysis [2, 3].

3. Importance of management of CKD in kidney transplant recipients and donors (Grade A, Level 4)

A number of kidney transplant recipients and donors have developed into CKD stage 3 to 5 after kidney transplantation and donor nephrectomy, respectively. Thus, long-term and periodical follow-up and management of CKD in both recipients and donors are important [4].

Kidney Disease Quality Measure Development, Maintenance, and Support

Practitioner Level Measurement of Effective Access to Kidney Transplantation
Technical Expert Panel
Relevant Measures

Contents

Measure Title	**Adult Kidney Disease: Transplant Referral**
Measure Developer	Not specified
Measure Description	Percentage of patients aged 18 years and older with a diagnosis of ESRD on hemodialysis or peritoneal dialysis for 90 days or longer who are referred to a transplant center for kidney transplant evaluation within a 12-month period
Numerator	Patients who are referred to a transplant center for kidney transplant evaluation within a 12-month period
Denominator	All patients aged 18 years and older with a diagnosis of ESRD on hemodialysis or peritoneal dialysis for 90 days or longer
Exclusions	Documentation of medical reason(s) for not referring for kidney transplant evaluation (eg, patient undergoing palliative dialysis, patient already approved by a qualified transplant program and scheduled to receive a living donor kidney transplant, other medical reasons) Documentation of patient reason(s) for not referring for kidney transplant evaluation (eg, patient declined, other patient reasons) Documentation of system reason(s) for not referring for kidney transplant evaluation (eg, lack of insurance coverage, nearest facility too far away, other system reasons)
NQF Endorsed	No
Clinical Condition	End Stage Renal Disease (ESRD)
Risk Adjusted	Not available
Link	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=3017

Measure Title	**Kidney Transplant Referral Rate for Prevalent Dialysis Patients**
Measure Developer	University of Michigan Kidney Epidemiology and Cost Center
Measure Description	This measure tracks the percentage of all patient months for patients at the dialysis facility who have ever been referred to a kidney transplant center as of the last day of each month during the reporting year. The measure as currently defined is intended for use in initial data collection to support alpha and beta testing.
Numerator	Number of patient months in which the patient has ever been referred to a kidney transplant center as of the last day of each month during the reporting year.
Denominator	All the patient months for patients who are under the age of 75 as of the last day of each month and who are assigned to the dialysis facility as of the last day of each month during the reporting year.
Exclusions	Exclusions that are implicit in the denominator include: Patients 75 years of age and older on the last day of each month during the reporting year Patients already on the kidney or kidney-pancreas waitlist There are no other exclusions for this measure.
NQF Endorsed	No
Clinical Condition	End Stage Renal Disease (ESRD)
Risk Adjusted	Not available
Link	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=5672

Measure Title	**Kidney Transplant Waitlist Decision Rate for Prevalent Dialysis Patients**
Measure Developer	University of Michigan Kidney Epidemiology and Cost Center
Measure Description	This measure tracks the percentage of all patient months for patients at the dialysis facility for which a kidney or kidney-pancreas transplant waitlist or living donor kidney transplant decision was made as of the last day of each month during the reporting year. The measure as currently defined is intended for use in initial data collection to support alpha and beta testing.
Numerator	Number of patient months in which a kidney or kidney-pancreas transplant waitlist or living donor kidney transplant decision was made for the patient as of the last day of each month during the reporting year.
Denominator	All the patient months for patients who are under the age of 75 on the last day of each month and who are assigned to the dialysis facility as of the last day of each month during the reporting year.
Exclusions	Exclusions that are implicit in the denominator include: Patients 75 years of age and older on the last day of each month during the reporting year. There are no other exclusions for this measure.
NQF Endorsed	No
Clinical Condition	End Stage Renal Disease (ESRD)
Risk Adjusted	Not available
Link	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=5671

Measure Title	**Standardized Kidney Transplant Referral Ratio for Incident Dialysis Patients**
Measure Developer	University of Michigan Kidney Epidemiology and Cost Center
Measure Description	This measure tracks the number of incident ESRD patients at the dialysis facility under the age of 75 who were referred to a kidney transplant center within the first year of initiating dialysis. The measure as currently defined is intended for use in initial data collection to support alpha and beta testing.
Numerator	Number of patients at the dialysis facility who were referred to a kidney transplant center within one year of starting dialysis.
Denominator	Number of patients under the age of 75 and not on the kidney or kidney-pancreas waitlist who were referred to a kidney transplant center that would be expected among eligible dialysis patients at the facility during the time period, given the patient mix at the facility.
Exclusions	Exclusions that are implicit in the denominator definition include: Patients at the facility who were 75 years of age and older at initiation of dialysis Patients at the facility who were referred to a transplant center prior to the initiation of dialysis Patients at the facility who were listed on the kidney or kidney-pancreas transplant waitlist prior to the initiation of dialysis There are no additional exclusions for this measure at this time.
NQF Endorsed	No
Clinical Condition	End Stage Renal Disease (ESRD)
Risk Adjusted	Not available
Link	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=5674

Measure Title	**Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)**
Measure Developer	University of Michigan Kidney Epidemiology and Cost Center
Measure 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	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. Data are currently aggregated across 3 years due to the low number of event rates. 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: - The patient is on the kidney or kidney-pancreas transplant waitlist or - The patient has received a living donor transplant.
Denominator	The denominator for the SWR is the expected number of wait listing 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 incident comorbidities, among patients under 75 years of age who were not already waitlisted prior to dialysis. 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, 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).
Exclusions	Exclusions that are implicit in the denominator definition include: - Patients at the facility who were 75 years of age and older at initiation of dialysis - Patients at the facility who were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis In addition, patients who were admitted to a skilled nursing facility (SNF) or hospice at the time of initiation of dialysis were excluded. 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. Hospice status is determined from a separate CMS file that contains final action claims submitted by Hospice providers. Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month.
NQF Endorsed	No
Clinical Condition	End Stage Renal Disease (ESRD)
Risk Adjusted	Not available
Link	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=5675

Measure Title	**Percentage of Prevalent Patients Waitlisted (PPPW)**
Measure Developer	University of Michigan Kidney Epidemiology and Cost Center
Measure Description	The PPPW measure tracks the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waiting list. Results are averaged across patients prevalent on the last day of each month during the reporting year, adjusted for age.
Numerator	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	The denominator for the PPPW is the sum of 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. Calculations will exclude the months covered by a granted ECE
Exclusions	Exclusions that are implicit in the denominator definition include: • Patients who were at age 75 or older in the reporting month. • Patient who were admitted to an SNF or a hospice during the month of evaluation were excluded from that month; patients who were admitted to an SNF at incidence or previously according to Form CMS-2728 were also excluded. The Nursing Home Minimum Dataset and the Questions 17u and 22 on the CMS Medical Evidence Form are used to identify patients in SNFs. For hospice patients, a separate CMS file that contains final action claims submitted by hospice providers was used to determine the hospice status.
NQF Endorsed	No
Clinical Condition	End Stage Renal Disease (ESRD)
Risk Adjusted	Not available
Link	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=5673

Measure Title	**Consultation with Nephrologist for Patients with Advanced Chronic Kidney Disease**
Measure Developer	Not available
Measure Description	Percentage of patients aged 18 through 89 years of age with: - two eGFR values < 30 ml/min/1.73m2 at least 90 days apart OR - two eGFR values < 45 ml/min/1.73m2 at least 90 days apart AND proteinuria or albuminuria for whom a consultation or visit with a nephrologist occurred within a 12 month period.
Numerator	Patients for whom a consultation or visit with a nephrologist occurred within a 12 month period.
Denominator	All patients aged 18 through 89 years with: - two eGFR values < 30 ml/min/1.73m2 at least 90 days apart OR - two eGFR values < 45 ml/min/1.73m2 at least 90 days apart AND proteinuria or albuminuria.
Exclusions	Patients with limited life expectancy, or receiving hospice care Patients with a diagnosis of end-stage renal disease (ESRD) or who had a renal transplant before or during the measurement period.
NQF Endorsed	No
Clinical Condition	End Stage Renal Disease (ESRD)
Risk Adjusted	Not available
Link	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=5970

Measure Title	**NQF# 0258: In-center hemodialysis patients' experiences: percentage of in-center hemodialysis patients who reported whether specified information was provided to them**
Measure Developer	Agency for Healthcare Research and Quality; CAHPS Consortium (Nov 15 2007; updated May 2009)
Measure Description	This measure is used to assess the percentage of respondents who indicated whether ("Yes" or "No"): • they know how to take care of their graft, fistula or catheter. • the dialysis center ever gave them any written information about their rights as a patient. • the dialysis center staff at the center ever reviewed their rights as a patient with them. • the dialysis center staff ever told them what to do if they experienced a health problem at home. • any dialysis center staff ever told them how to get off the machine if there is an emergency at the center. • their kidney doctors or dialysis center staff talked to them as much as they wanted about which treatment is right for them. • their doctor or dialysis center staff explained to them why they are not eligible for a kidney transplant. • their kidney doctors or dialysis center staff talked to them about peritoneal dialysis. • they were as involved as much as they wanted in choosing the treatment for kidney disease that is right for them. The "Providing Information to Patients" composite measure is based on nine questions in the CAHPS In-Center Hemodialysis Survey.
Numerator	All currently dialyzing in-center hemodialysis patients, age 18 years and older, who answered the "Providing Information to Patients" questions on the CAHPS In-Center Hemodialysis Survey. Include refusals, non-responders (never responded, was unavailable at the time of the survey, was ill or incapable, had a language barrier, etc.), and bad addresses/phone numbers. The number of responses ("Yes" or "No") on the "Providing Information to Patients" questions (see the related "Numerator Inclusions/Exclusions" field)
Denominator	All currently dialyzing in-center hemodialysis patients, age 18 years and older, who answered the "Providing Information to Patients" questions on the CAHPS In-Center Hemodialysis Survey (see the related "Denominator Inclusions/Exclusions" field)
Exclusions	Deceased

	Ineligible. The respondent has been a patient at the facility for less than three months, is not a patient at the facility, or is no longer receiving in-center hemodialysis (received a transplant or has switched to peritoneal dialysis).
NQF Endorsed	Yes
Clinical Condition	Chronic kidney disease/end-stage renal disease
Risk Adjusted	Case-mix adjustment; CAHPS recommends adjusting the data for respondent age, education, and self-reported health status.
Link	http://www.qualitymeasures.ahrq.gov/content.aspx?id=26589&search=kidney+transplant+access

Measure Title	**Percent of patients who have been referred for a transplant evaluation**
Measure Developer	Renal Physicians Association (RPA) (October 2002)
Measure Description	This measure assesses the percent of patients who have been referred for a transplant evaluation among patients with advanced chronic kidney disease (CKD), who are willing for a transplant, do not have an unacceptable level of surgical risk, and satisfy the United Network for Organ Sharing (UNOS) criteria for transplant candidacy.
Numerator	The number of patients from the denominator who have been referred for a transplant evaluation
Denominator	The number of adult patients with advanced chronic kidney disease (CKD) not currently receiving renal replacement therapy who are willing for a transplant, do not have an unacceptable level of surgical risk, and satisfy the United Network for Organ Sharing (UNOS) criteria for transplant candidacy
Exclusions	Unspecified
NQF Endorsed	No
Clinical Condition	Advanced chronic kidney disease
Risk Adjusted	No
Link	http://www.qualitymeasures.ahrq.gov/content.aspx?id=28242&search=kidney+transplant

Measure Title	**Percent of patients with documentation regarding discussion of renal replacement therapy (RRT) modalities**
Measure Developer	Renal Physicians Association (RPA) (November 2002)
Measure Description	This measure assesses the percent of patients with advanced chronic kidney disease (CKD) with documentation regarding discussion of renal replacement therapy (RRT) modalities.
Numerator	The number of patients from the denominator with documentation regarding discussion of renal replacement therapy (RRT) modalities
Denominator	The number of adult patients with advanced chronic kidney disease (CKD) not currently receiving renal replacement therapy
Exclusions	Unspecified
NQF Endorsed	No
Clinical Condition	Advanced chronic kidney disease
Risk Adjusted	No
Link	http://www.qualitymeasures.ahrq.gov/content.aspx?id=28241

Measure Title	**Percentage of all ESRD patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities conducted by facility personnel at least once during the 12-month reporting period**
Measure Developer	Kidney Care Quality Alliance (KCQA), Kidney Care Partners (KCP) (Feb 2010; updated Mar 2012)
Measure Description	This measure is used to assess the percentage of all end stage renal disease (ESRD) patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) conducted by facility personnel at least once during the 12-month reporting period.
Numerator	Number of patients from the denominator with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) conducted by facility personnel at least once during the 12-month reporting period (see the related "Numerator Inclusions/Exclusions" field)
Denominator	All end stage renal disease (ESRD) patients aged 18 years and older (see the related "Denominator Inclusions/Exclusions" field)
Exclusions	None
NQF Endorsed	No
Clinical Condition	End stage renal disease (ESRD)
Risk Adjusted	No
Link	http://www.qualitymeasures.ahrq.gov/content.aspx?id=34209&search=kidney+transplant

Measure Title	**Percentage of all ESRD patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities conducted by the nephrologist or other healthcare professional within the nephrologist's practice at least once during the 12-month reporting period**
Measure Developer	Kidney Care Quality Alliance (KCQA), Kidney Care Partners (KCP) (Feb 2010; updated Mar 2013)
Measure Description	This measure is used to assess the percentage of all end stage renal disease (ESRD) patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) conducted by the nephrologist or other healthcare professional within the nephrologist's practice at least once during the 12-month reporting period.
Numerator	Number of patients from the denominator with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) conducted by the nephrologist or other healthcare professional within the nephrologist's practice at least once during the 12-month reporting period (see the related "Numerator Inclusions/Exclusions" field)
Denominator	All end stage renal disease (ESRD) patients aged 18 years and older receiving renal replacement therapy (see the related "Denominator Inclusions/Exclusions" field)
Exclusions	None
NQF Endorsed	No
Clinical Condition	ESRD
Risk Adjusted	No
Link	http://www.qualitymeasures.ahrq.gov/content.aspx?id=34212&search=kidney+transplant

Measure Title	**Percent of patients with documentation regarding discussion of renal replacement therapy (RRT) modalities**
Measure Developer	Renal Physicians Association (RPA) (October 2002)
Measure Description	This measure assesses the percent of patients with advanced chronic kidney disease (CKD) with documentation regarding discussion of renal replacement therapy (RRT) modalities.
Numerator	The number of patients from the denominator with documentation regarding discussion of renal replacement therapy (RRT) modalities
Denominator	The number of adult patients with advanced chronic kidney disease (CKD) not currently receiving renal replacement therapy
Exclusions	Unspecified
NQF Endorsed	No
Clinical Condition	Advanced chronic kidney disease
Risk Adjusted	Not stated
Link	http://www.qualitymeasures.ahrq.gov/content.aspx?id=28241&search=kidney+replacement

Measure Title	**HHS #5598: Proportion of dialysis patients waitlisted and/or receiving a deceased donor kidney transplant within 1 year of end-stage renal disease (ESRD) start (among patients under 70 years of age). (Healthy People 2020 Chronic Kidney Disease - 12 [CKD - 12])**
Measure Developer	U.S. Department of Health & Human Services: Office of the Assistant Secretary for Health (ASH) (2008; updated Apr 2013)
Measure Description	This measure assessed the proportion of dialysis patients waitlisted and/or receiving a deceased donor kidney transplant within 1 year of end-stage renal disease (ESRD) start among patients under 70 years of age.
Numerator	Number of persons under age 70 years registered on the kidney transplant waiting list or receiving a decreased donor kidney within one year of initiation of renal replacement therapy
Denominator	Number of incident persons on renal replacement therapy under age 70 years in a year; does not include living donor kidney transplant recipients
Exclusions	Unspecified
NQF Endorsed	No
Clinical Condition	Chronic kidney disease
Risk Adjusted	Unspecified
Link	http://www.qualitymeasures.ahrq.gov/hhs/content.aspx?id=45802&search=kidney%20transplant

Measure Title	**HHS #5632: Proportion of patients with treated chronic kidney failure who receive a transplant within 3 years of registration on the waiting list. (Healthy People 2020 Chronic Kidney Disease - 13.1 [CKD - 13.1])**
Measure Developer	U.S. Department of Health & Human Services: Office of the Assistant Secretary for Health (ASH) (2008; updated Apr 2012)
Measure Description	This measure assesses the proportion of patients with treated chronic kidney failure who receive a transplant within 3 years of registration on the waiting list among patients under 70 years of age.
Numerator	Number of persons under age 70 years receiving a kidney transplant within three years of initiation of renal replacement therapy
Denominator	Number of incident persons on renal replacement therapy under age 70 years
Exclusions	Unspecified
NQF Endorsed	No
Clinical Condition	Chronic kidney disease
Risk Adjusted	Unspecified
Link	http://www.qualitymeasures.ahrq.gov/hhs/content.aspx?id=45836&search=kidney%20transplant

Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel 2021

KIDNEY EPIDEMIOLOGY
AND COST CENTER
UNIVERSITY OF MICHIGAN

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Agenda

2:00 pm:	Introductions and Conflicts of Interest
2:35 pm:	Measure Development Process
2:45 pm:	Roles of TEP and TEP Co-Chairs
2:50 pm:	TEP Charter
3:00 pm:	Background – Access to Kidney Transplantation
3:30 pm:	Background – Access to Transplant Measures
3:45 pm:	Wrap Up
3:50 pm:	Public Comment Period

All times listed are Eastern Daylight Time

Introductions and Conflicts of Interest

- TEP members must disclose any current and past activities that may cause a conflict of interest. This includes financial interests or other relationships that may influence their perceptions or judgement.
- It is unethical to conceal (or fail to disclose) conflicts of interest. However, the disclosure requirement is not intended to prevent individuals with particular perspectives or strong points of view from serving on the TEP. The intent of full disclosure is to inform the measure developer, other TEP members, and CMS about the source of TEP members' perspectives and how that might affect discussions or recommendations.
- If a member's status changes and a potential conflict of interest arises at any time while a member is serving on the TEP, the TEP member is required to notify the measure developer and the TEP chair.

Source: A Blueprint for the CMS Measures Management System
Version 14.0

TEP Members

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
Co-Chair: Rachel Patzer, PhD, MPH, Director, Health Services Research Center	Emory University School of Medicine Atlanta, GA	None
Co-Chair: Bobby Howard Patient, Director, Multicultural Donation Education Program	LifeLink of Georgia Association of Organ Procurement Norcross, GA	None
David Axelrod, MD, MBA Transplant Surgeon	University of Iowa Iowa City, IA	Consulting arrangements with CareDx and Talaris; active research into outcomes after kidney and liver transplant using linked datasets.
Bryan N. Becker, MD, MMM Physician	DaVita, Inc. Hinsdale, IL	Employed by DaVita, Inc., and own DaVita, Inc. stock.
Teri Browne, PhD, MSW Associate Dean and Professor	University of South Carolina College of Social Work Irmo, SC	None
Sasha Couch Patient	Renal Support Network Los Angeles, CA	None
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Dawn P. Edwards Patient	National Forum of ESRD Networks Kidney Patient Advisory Council Jamaica, NY	None

TEP Members

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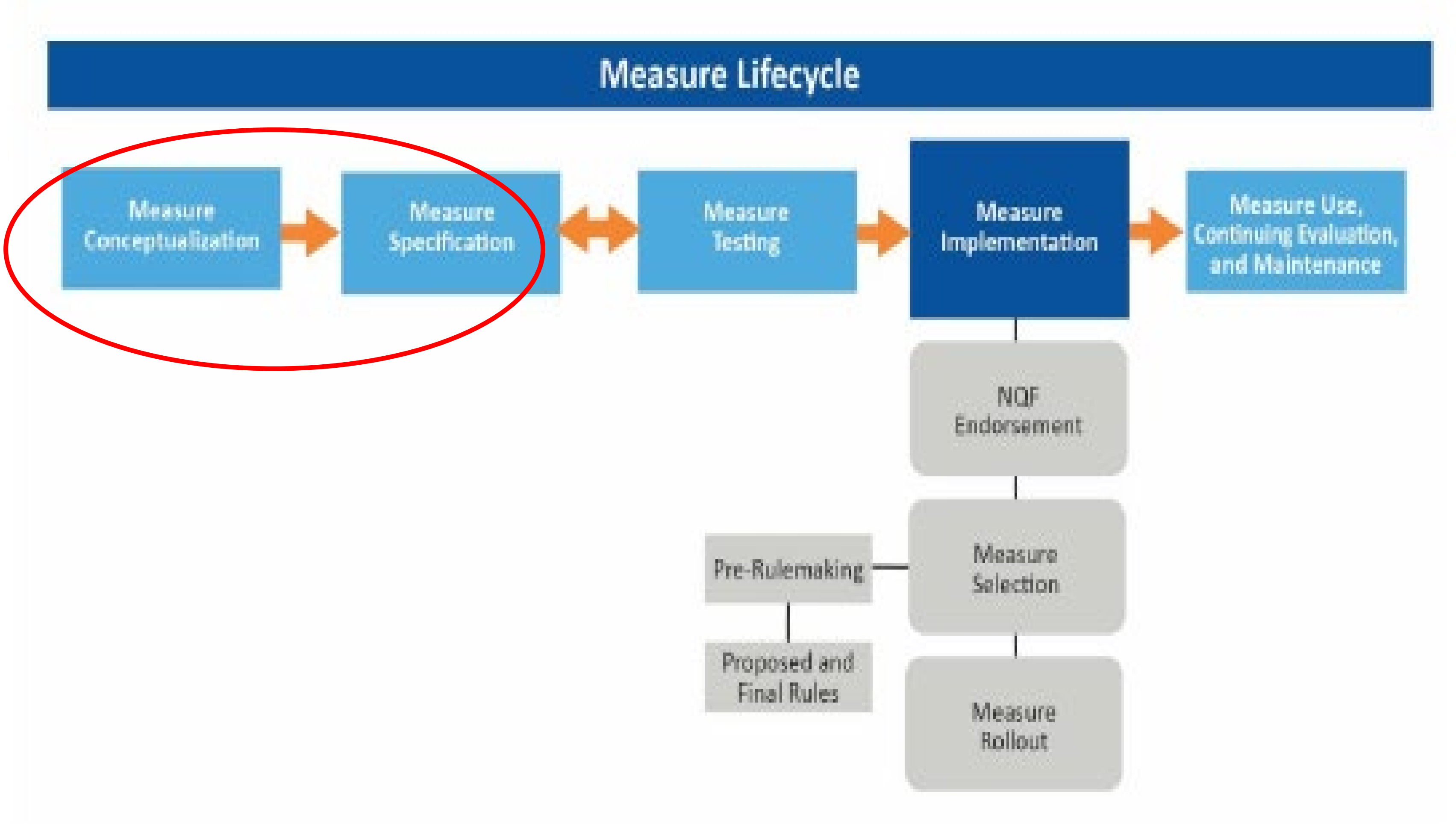
Measure Development Process

Measure Development, Implementation, and Maintenance Process



Measure Lifecycle

Measure Conceptualization → Measure Specification ↔ Measure Testing → Measure Implementation → Measure Use, Continuing Evaluation, and Maintenance

Source: A Blueprint for the CMS Measures Management System
Version 16.0

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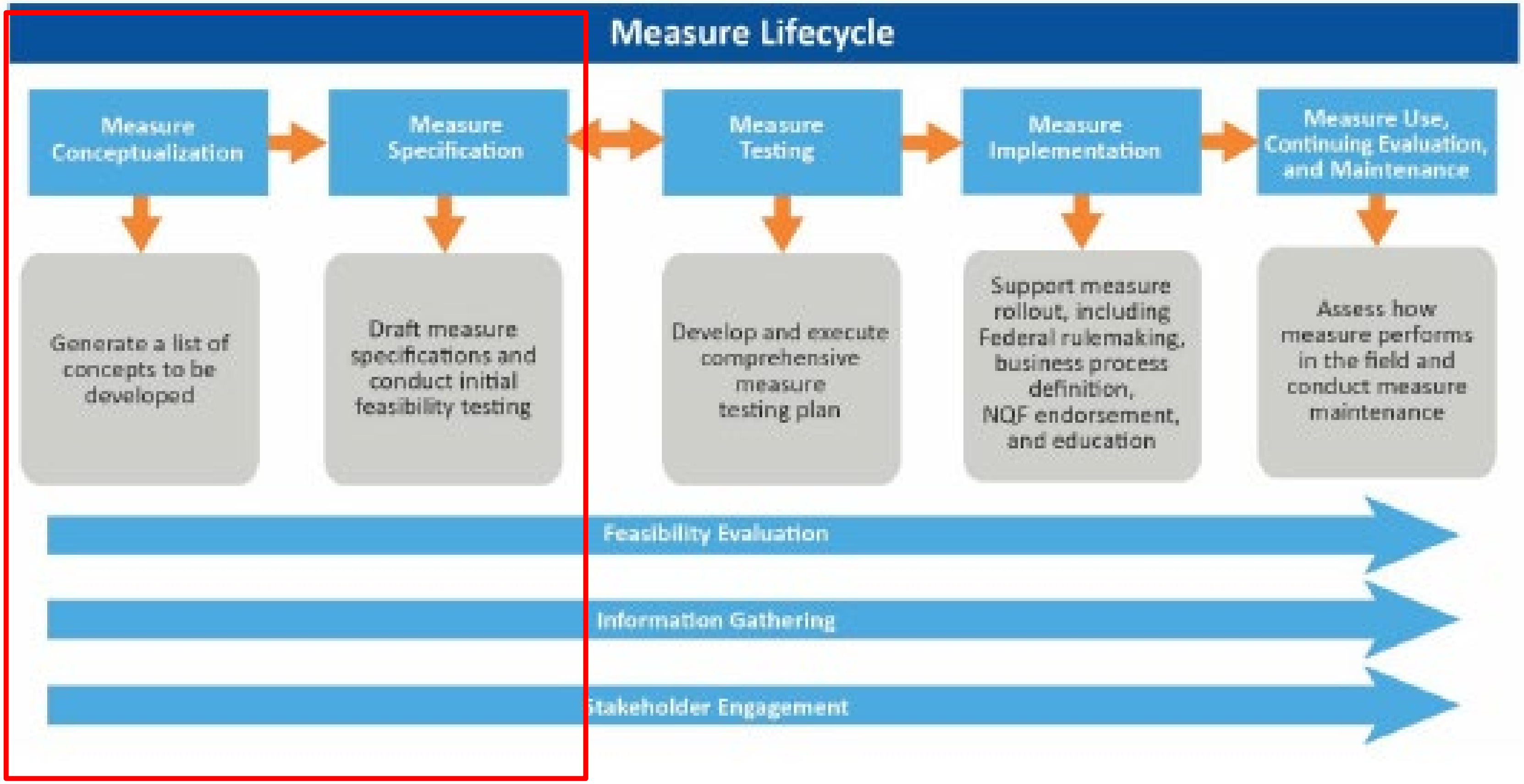
Measure Development, Implementation, and Maintenance Process



Measure Lifecycle

Measure Conceptualization: Generate a list of concepts to be developed

Measure Specification: Draft measure specifications and conduct initial feasibility testing

Measure Testing: Develop and execute comprehensive measure testing plan

Measure Implementation: Support measure rollout, including Federal rulemaking, business process definition, NQF endorsement, and education

Measure Use, Continuing Evaluation, and Maintenance: Assess how measure performs in the field and conduct measure maintenance

Feasibility Evaluation

Information Gathering

Stakeholder Engagement

Source: A Blueprint for the CMS Measures Management System Version 16.0

Measure Evaluation Criteria

- Importance to Measure and Report
  - Evidence
  - Performance Gap
  - Priority to report measure outcome
- Scientific Acceptability
  - Reliability and Validity of measure
- Feasibility
  - Ability to obtain data to calculate measure
- Usability
  - Measure results are actionable to help improve performance
- Harmonization
  - Comparison to any related or competing measures

Role of the TEP

Duties and Role of TEP members:

- Help develop measure areas
- Review and discuss evidence to determine the basis of support for the proposed measure(s)
- Recommend draft measure specifications
- Review and approve summary report recommendations of the TEP Meeting, draft and final measure specifications, and provide input on other necessary documentation forms required for submission to the NQF for endorsement or for responses to public comments
- Be available for follow up conference calls, as needed

Role of the TEP

Role of UM-KECC (developer/contractor):

- Support the development of measures that are used in CMS quality programs, either for payment or public reporting.
- Work with the TEP chair(s) to ensure the panel discussions focus on the development of draft measure specifications, as recommended to the developer/contractor.
- Advise the TEP and the TEP chairs on the needs and requirements of the CMS contract and the timeline, and provide specific guidance and criteria that must be met with respect to CMS and NQF review of candidate measures.

Role of TEP chairs:

- The TEP chairs are responsible, in partnership with UM-KECC, for directing the TEP to meet the expectations for TEP members, including provision of advice to the developer/contractor regarding measure specifications.
  - Conduct the meeting according to the agenda.
  - Recognize speakers and call for votes when needed.

Role of the TEP

- TEPs are advisory to the measure developer/contractor (UM-KECC), and not CMS
- It is the responsibility of UM-KECC to consider input received by the TEP; however recommendations made to CMS are made by UM-KECC, and not by the TEP
- If UM-KECC makes recommendations to CMS that are not consistent with the recommendations from the TEP, it is the measure developer's responsibility to explain the rationale for any differences

Source: A Blueprint for the CMS Measures Management System
Version 14.0

Transplant TEP Charter

- Benefits of kidney transplantation are well established
- Increasing access to kidney transplantation is a national priority
- The TEP will use existing data and their expert opinion to formulate recommendations to UM-KECC regarding the development of new **practitioner level** measures to assess effective access to kidney transplantation
- Measures other than at the practitioner level can also be discussed and considered

Background: Access to Kidney Transplantation

Overview

- Benefits of kidney transplantation
- Path to kidney transplantation
- Education/Knowledge
- Referral
- Waitlisting/Living Donor Transplantation
- Interventions to improve transplant access

Benefits of Kidney Transplantation - Survival

- No trials comparing transplantation vs dialysis
- Observational comparisons between transplanted patients and waitlist controls

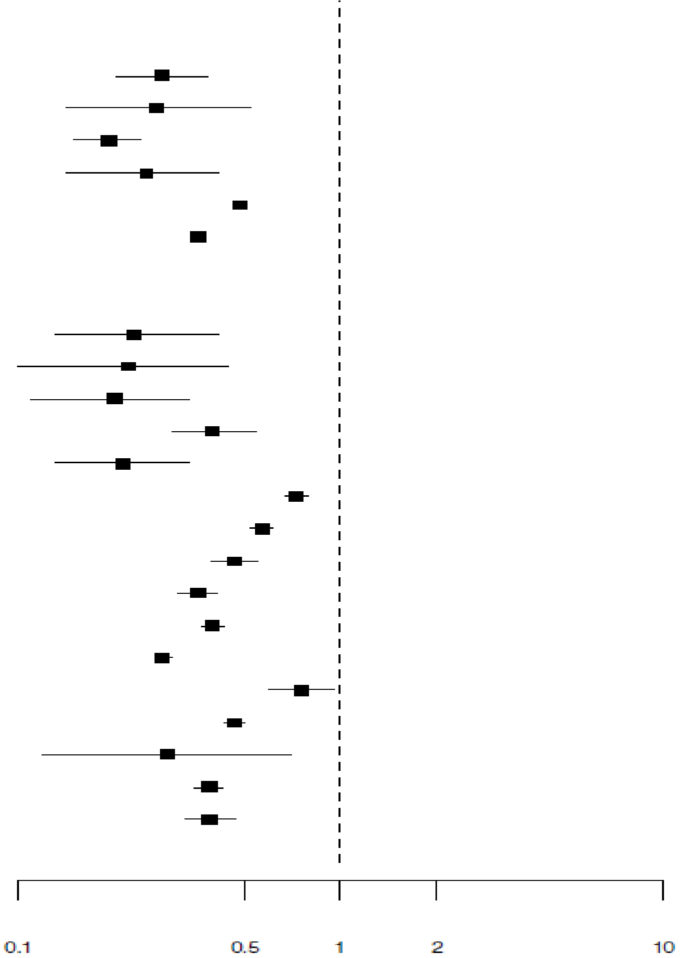
Patient Group	Life Expectancy Without Transplant (y)	Life Expectancy With Transplant (y)
Overall	10	20
Age 20-39, no diabetes	20	31
Age 20-39, diabetes	8	25
Age 40-59, no diabetes	12	19
Age 40-59, diabetes	8	22
Age 60-74, no diabetes	7	12
Age 60-74, diabetes	5	8

Wolfe et al, NEJM 1999

Benefits of Kidney Transplantation - Survival

> 1 year	
Transplant vs Dialysis	
Oniscu 2005*	0.28 (0.20, 0.39)
Oniscu 2004*	0.27 (0.14, 0.52)
McDonald 2002*	0.19 (0.15, 0.24)
Rabbat 2000*	0.25 (0.14, 0.42)
Ojo 1994*	0.49 P < 0.03
Port 1993*	0.36 P ≤ 0.001
Full follow-up	
Transplant vs Dialysis	
Bayat 2010 < 60 y	0.23 (0.13, 0.42)
Bayat 2010 ≥ 60 y	0.22 (0.10, 0.45)
Jain 2009	0.20 (0.11, 0.34)
Sorensen 2007 nDM	0.40 (0.30, 0.55)
Sorensen 2007 DM	0.21 (0.13, 0.34)
Snyder 2006 nDM/nPAD*	0.73 (0.68, 0.79)
Snyder 2006 DM/nPAD*	0.57 (0.52, 0.62)
Snyder 2006 nDM/PAD*	0.47 (0.40, 0.56)
Snyder 2006 DM/PAD*	0.36 (0.31, 0.41)
Merion 2005 ECD*	0.40 (0.37, 0.44)
Merion 2005*	0.28 (0.27, 0.30)
Abbott 2004 HCV+donor	0.76 (0.60, 0.96)
Abbott 2004 HCV-donor	0.47 (0.44, 0.50)
Brunkhorst 2003*	0.29 (0.12, 0.70)
Glanton 2003 nObese*	0.39 (0.35, 0.43)
Glanton 2003 Obese*	0.39 (0.33, 0.47)

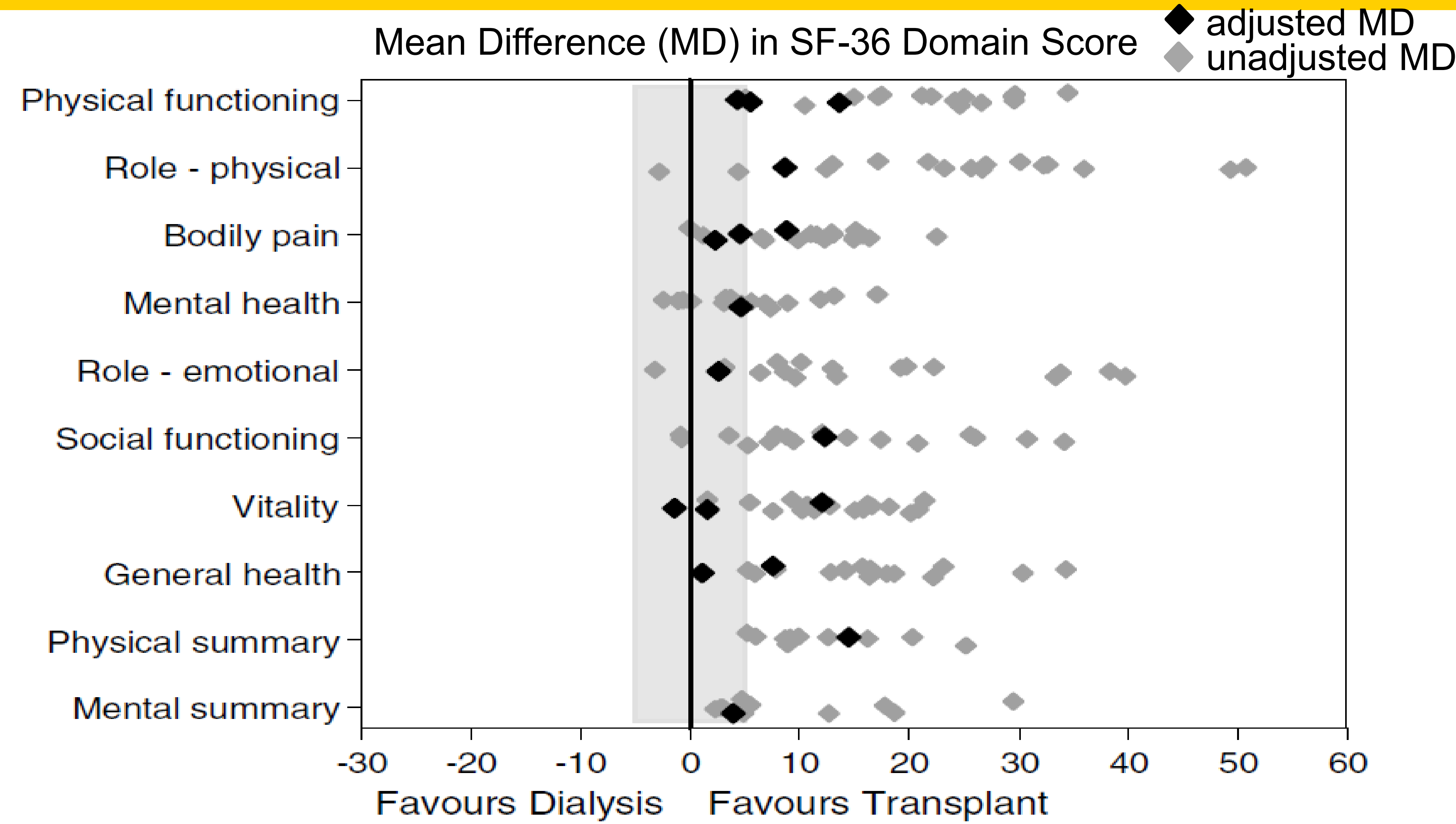
Hazard of all-cause mortality



Favors Transplant

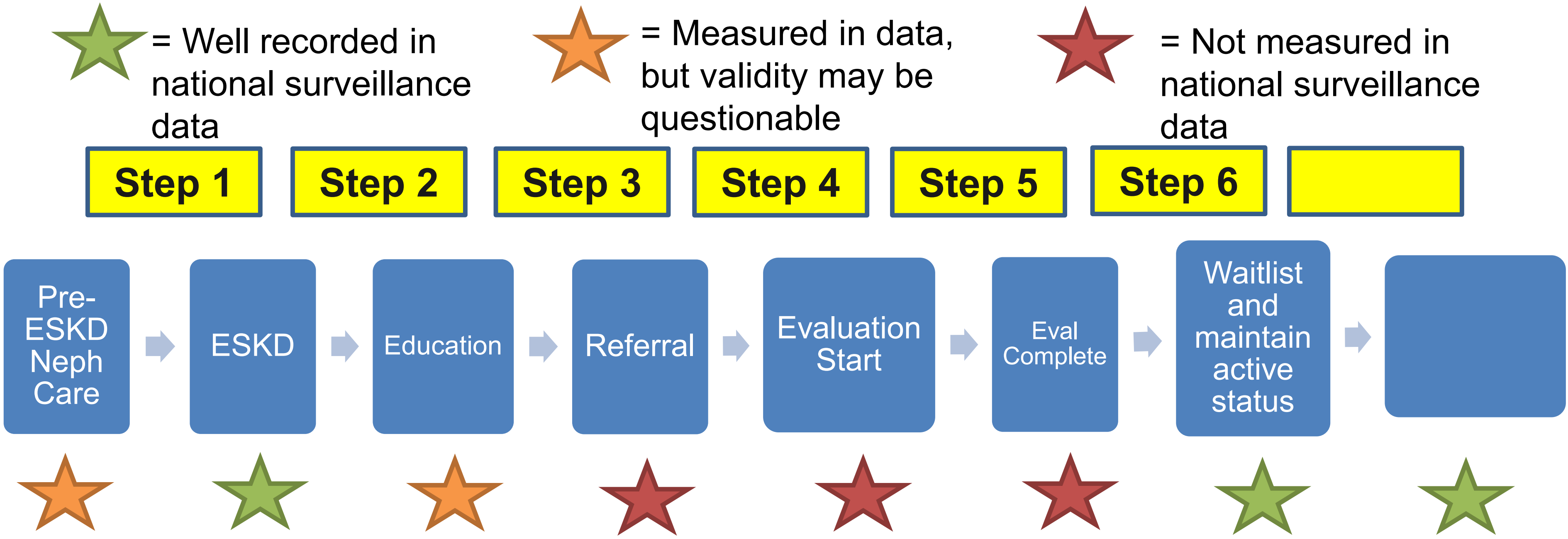
Meta-Analysis by Tonelli et al, AJT 2011

Benefits of Kidney Transplantation: Quality of Life



Meta-Analysis by Tonelli et al, AJT 2011

Steps to Kidney Transplant in the U.S.



🟩 = Well recorded in national surveillance data

🟧 = Measured in data, but validity may be questionable

🟥 = Not measured in national surveillance data

Step 1 **Step 2** **Step 3** **Step 4** **Step 5** **Step 6**

Pre-ESKD Neph Care	ESKD	Education	Referral	Evaluation Start	Eval Complete	Waitlist and maintain active status	
🟧	🟩	🟧	🟥	🟥	🟥	🟩	🟩

1. Kim JASN 2012; 23(6)
2. Salter JASN 2014; 25(12)

Knowledge/Education for Transplant Option

- 30% of patients not informed of kidney transplant option on Form 2728 at time of its filing (data from 2005-2007)
- Uninformed patients were less than half as likely to eventually be waitlisted or receive a living donor transplant

- In a survey of nephrologists (n=906) 81% felt ideally that >20 minutes of time should be spent educating patients on the kidney transplant option
- Only 43% of nephrologists reported spending > 20 minutes, with those at for-profit centers less likely to do so

Kucirka et al, AJT 2012; Balhara et al, AJT 2012

Knowledge/Education for Transplant Option

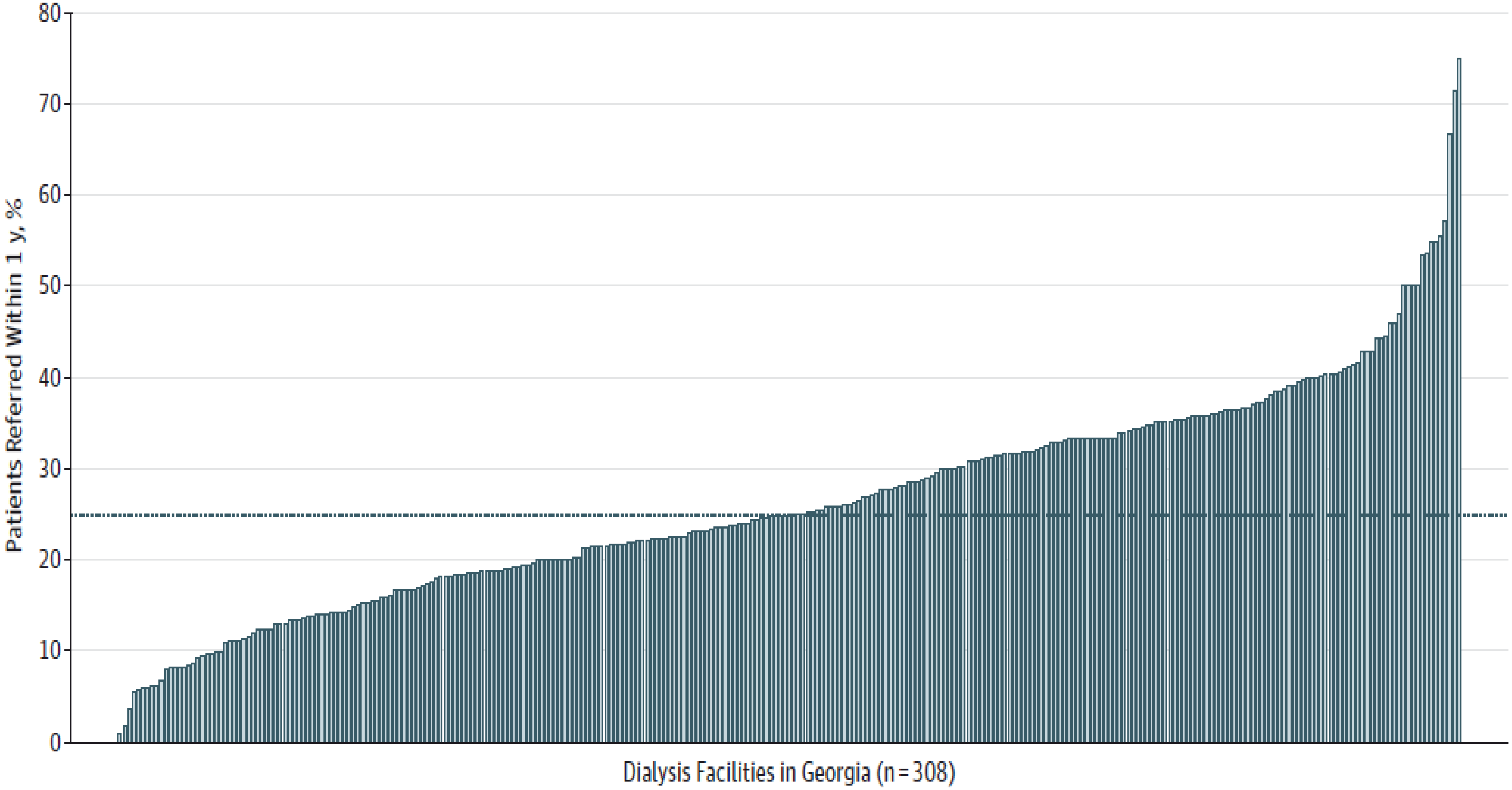
- Patient survey data (n=358) show substantial discordance with reported information on Form 2728 about transplant option
- Of patients marked as having received information on Form 2728, a third report never being informed about transplant
- Waitlisting was much more strongly associated (3-fold) with patient report of receiving information rather than as noted in Form 2728

- Survey of transplant educators (nurses, social workers) at dialysis facilities showed only 18% reporting in depth discussion of risks and benefits of transplant
- Facilities with educators using more than three educational strategies had higher rates of waitlisting

Salter et al, JASN 2014; Waterman et al, CJASN 2015

Referral for Transplant Evaluation

Figure 2. Percentages of Patients With End-Stage Renal Disease Referred for Kidney Transplantation Within 1 Year of Starting Dialysis Among Georgia Dialysis Facilities: 2005-2011



Patzer et al, JAMA 2015

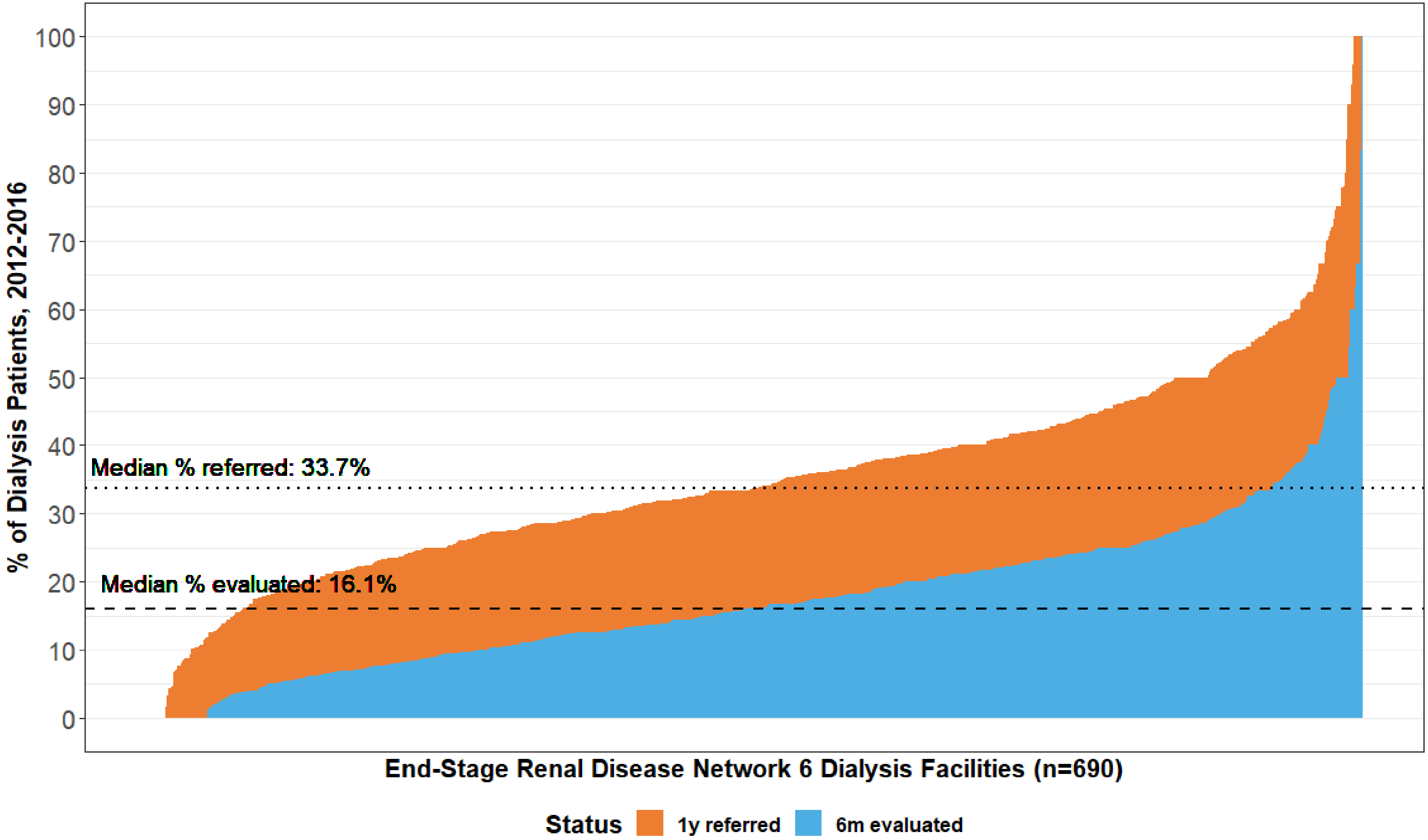
Referral for Kidney Transplantation

- The median rate of referral within a year of dialysis start was 24%, ranging from facilities with 0% to 75% of their patients referred
- Factors associated with non-referral included white race, older age, more comorbidities

- Of patients referred, only 21% were waitlisted or received a transplant within one year of referral
- Black race was associated with a lower likelihood of waitlisting within a year of referral

Patzer et al, JAMA 2015

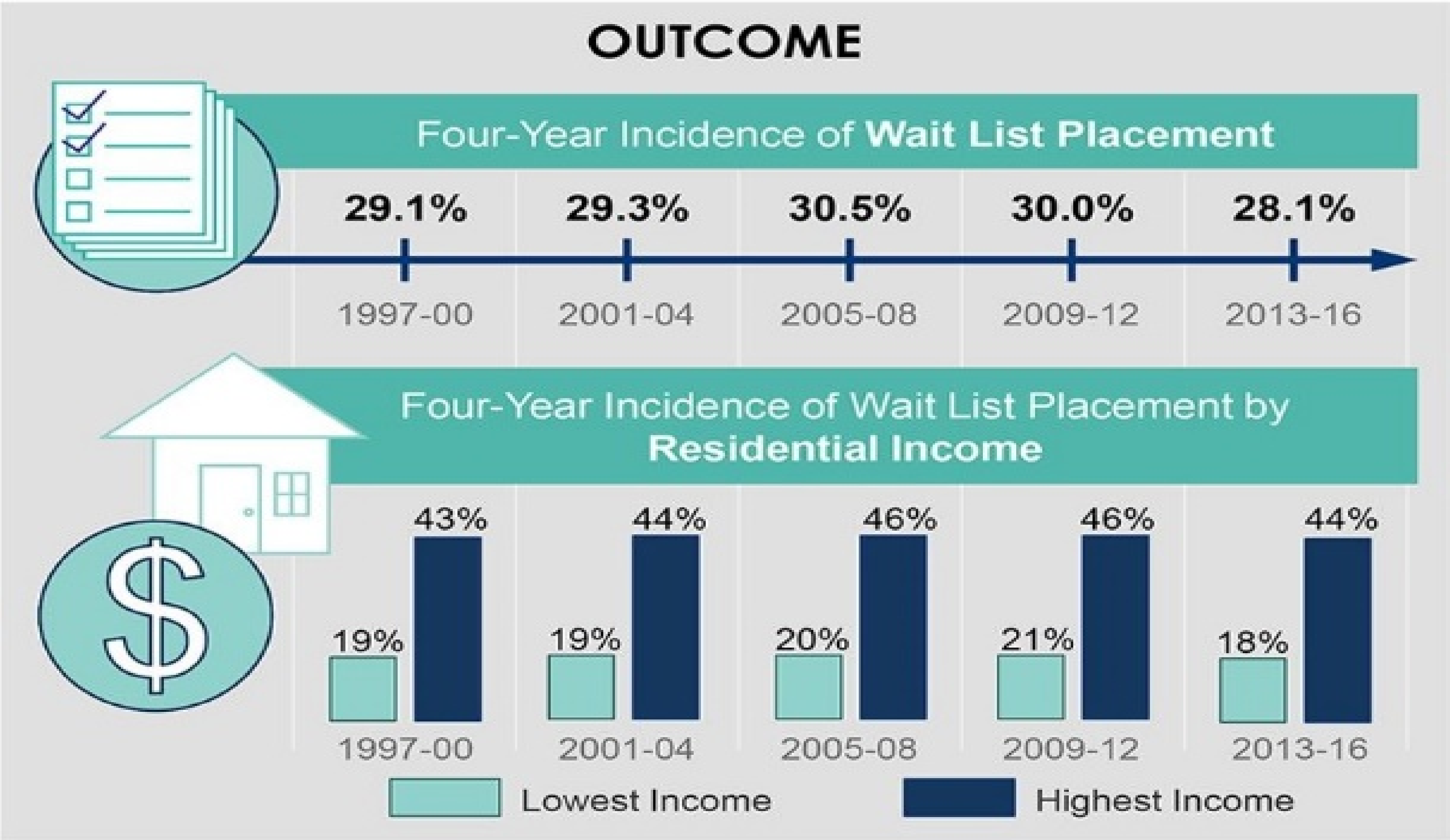
Referral and Evaluation Start Among Dialysis Facilities in GA, NC, SC



Patzer et al, AJT 2020

Patzer RE et al. AJT 2020

Waitlisting for Kidney Transplantation



Schold et al, JASN 2021 Visual Abstract

Waitlisting for Kidney Transplantation - Disparities

Persistent racial/ethnic disparities in waitlisting over time (Schold et al, JASN 2021)

Race/Ethnicity	1997-2000	2001-2004	2005-2008	2009-2012	2013-2016
NH White	32.7	31.9	32.1	30.4	28.3
NH Black	22.9	23.2	25.3	25.9	24.4
Asian	45.3	49.3	48.9	49.4	47.4
Hispanic White	31.7	32.5	34.3	33.8	30.8
Hispanic Black	27.7	29.2	31.6	26.7	29.2

- In post-KAS study examination of waitlist activity transitions, Black patients were less likely to resolve inactive status on the waitlist (Kulkarni et al, JAMA Surgery 2019)
- From 1995 to 2014, widening gap in likelihood of living donor kidney transplantation in non-Hispanic Blacks vs non-Hispanic Whites (Purnell et al, JAMA 2018)

Interventions to improve access to transplantation

- RaDIANT study (>9000 pts, 134 dialysis facilities), multi-level, multi-component intervention to increase facility referrals for transplantation and reduce disparities (Patzer et al, JASN 2017)
- Intervention vs control groups increased referral (adjusted mean difference of 7.3%), with a greater increase in Black patients

- Randomized study (n=470 pts) of iChoose Kidney web and mobile based decision aid (Patzer et al, AJT 2018)
- Intervention increased transplant knowledge more than control, but did not impact transplant access based on donor inquiry, waitlisting or receipt of transplant

Interventions to improve access to transplantation

- A 3 arm trial (n=561 pts, primarily Black or low income) of the Explore Transplant@Home educational intervention, either patient or educator guided (Waterman et al, AJKD 2019)
- Patients in the intervention arms demonstrated greater gains in knowledge about living and deceased donor transplantation

- Studies of patient navigator based interventions have shown no benefit (Sullivan et al, CJASN 2018), or modest effects on likelihood of waitlisting limited to ≥500 days beyond the referral (Basu et al, CJASN 2018)

Summary

- Limited progress in improving access to kidney transplantation over the last 2 decades
- Persistent disparities in access to transplantation by race/ethnicity and socio-economic status
- Interventions have been shown to improve knowledge about transplant, and referral, but effects on access to transplant further downstream are uncertain

Questions?

Background: Access to Kidney Transplant Measures

Access to Transplant Measures

- Prior Access to Transplant TEP 2004-2005 by ESRD Networks 9 and 10 – focused on importance of referral
- TEP in April 2015 organized by UM-KECC with mandate to develop dialysis facility quality measures
- 11 member panel

Access to Transplant Measures

2015 TEP discussion around 5 main measure areas:

- Patient Education on Kidney Transplantation
- Referral for Kidney Transplant Evaluation
- Waitlisting for Kidney Transplantation
- Tracking of Transplant Evaluation Process
- Transplantation Rate or Standardized Transplantation Ratio

Access to Transplant Measures

- Waitlisting chosen as focus to proceed with measure development (TEP voting: 8 to 3 in favor)

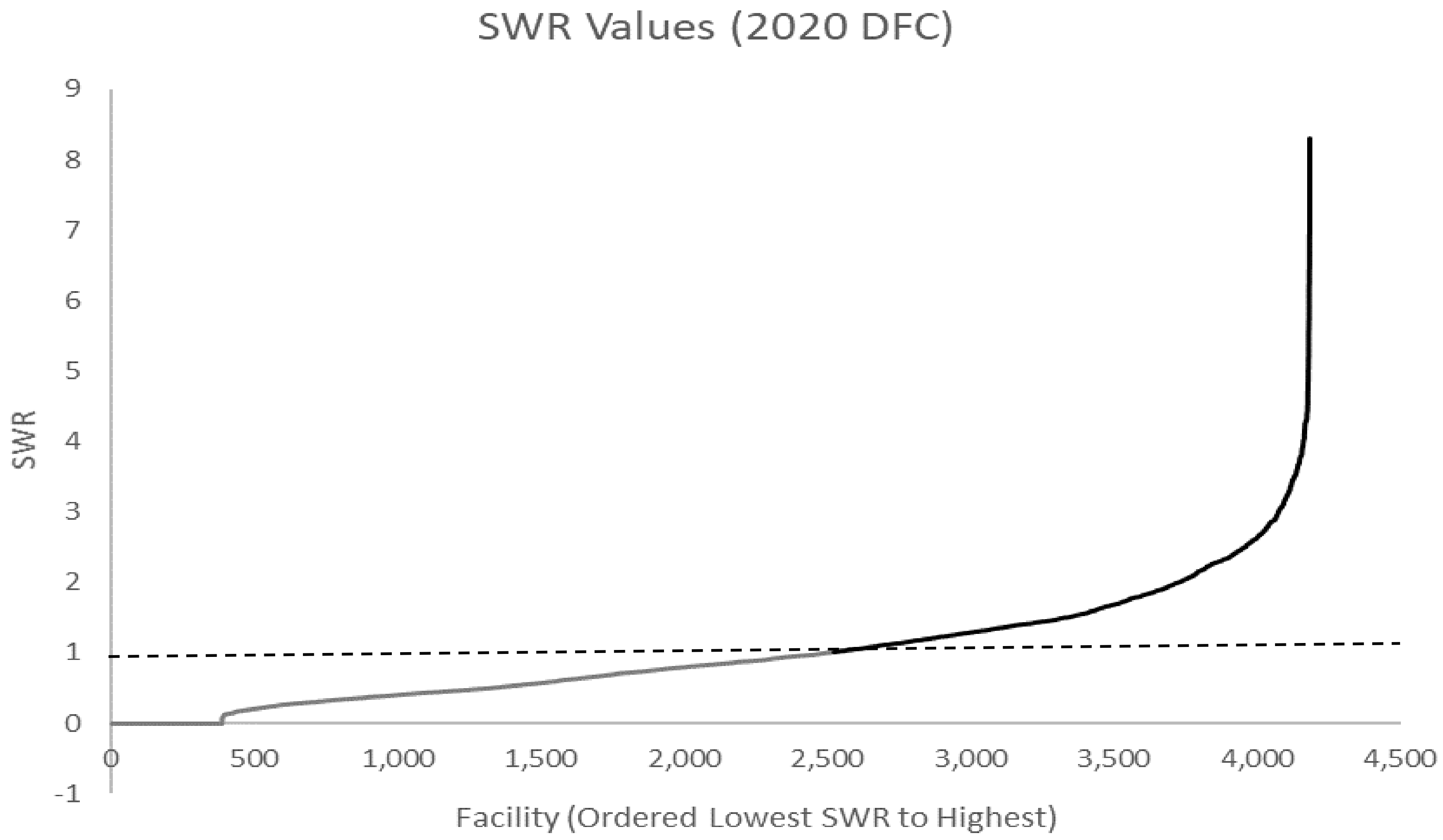
- Standardized First Kidney Transplant Waitlist Ratio (SWR)
- Focuses on first year after initiation of dialysis, encourage early waitlisting

- Percentage of Prevalent Patients Waitlisted (PPPW)
- Longer term focus, ongoing maintenance of patients on the waitlist

Access to Transplant Measures – SWR specs

- **Numerator**: Observed events of waitlisting (kidney or kidney-pancreas), or living donor kidney transplantation within first year of dialysis initiation
- **Denominator**: Expected number of events
- **Exclusions**: Age 75 years or older at incidence of dialysis, admitted to skilled nursing facility, admitted to hospice, waitlisted prior to initiation of dialysis
- **Risk Adjustment**: Age, incident comorbidities
- **Other**: Aggregated over 3 years

Access to Transplant Measures – SWR Data



Access to Transplant Measures – PPPW specs

- **Numerator**: No. of patient months in which patients at the dialysis facility are on the kidney or kidney-pancreas transplant waitlist as of the last day of each month during the reporting year.
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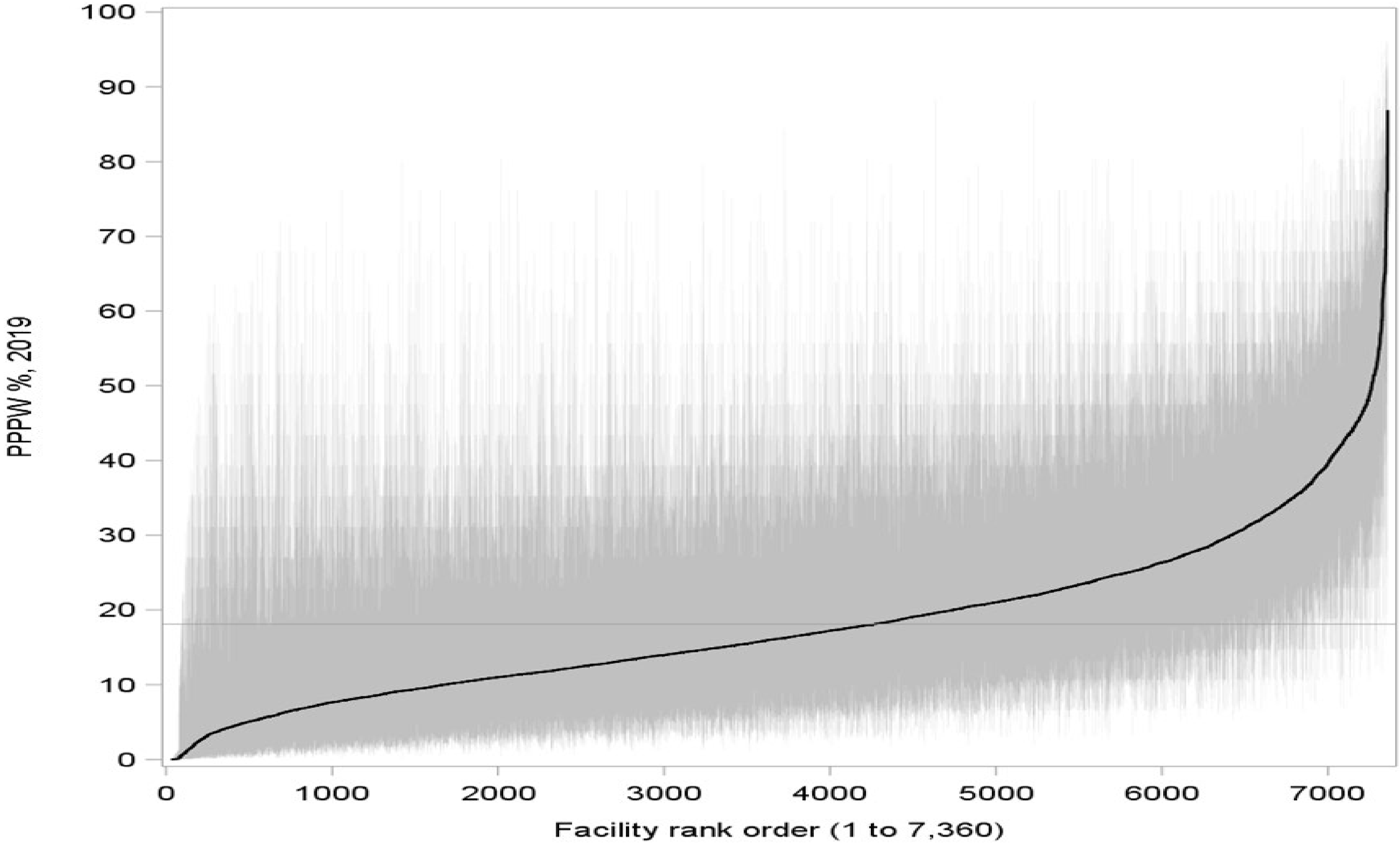


Access to Transplant Measures - Follow-up

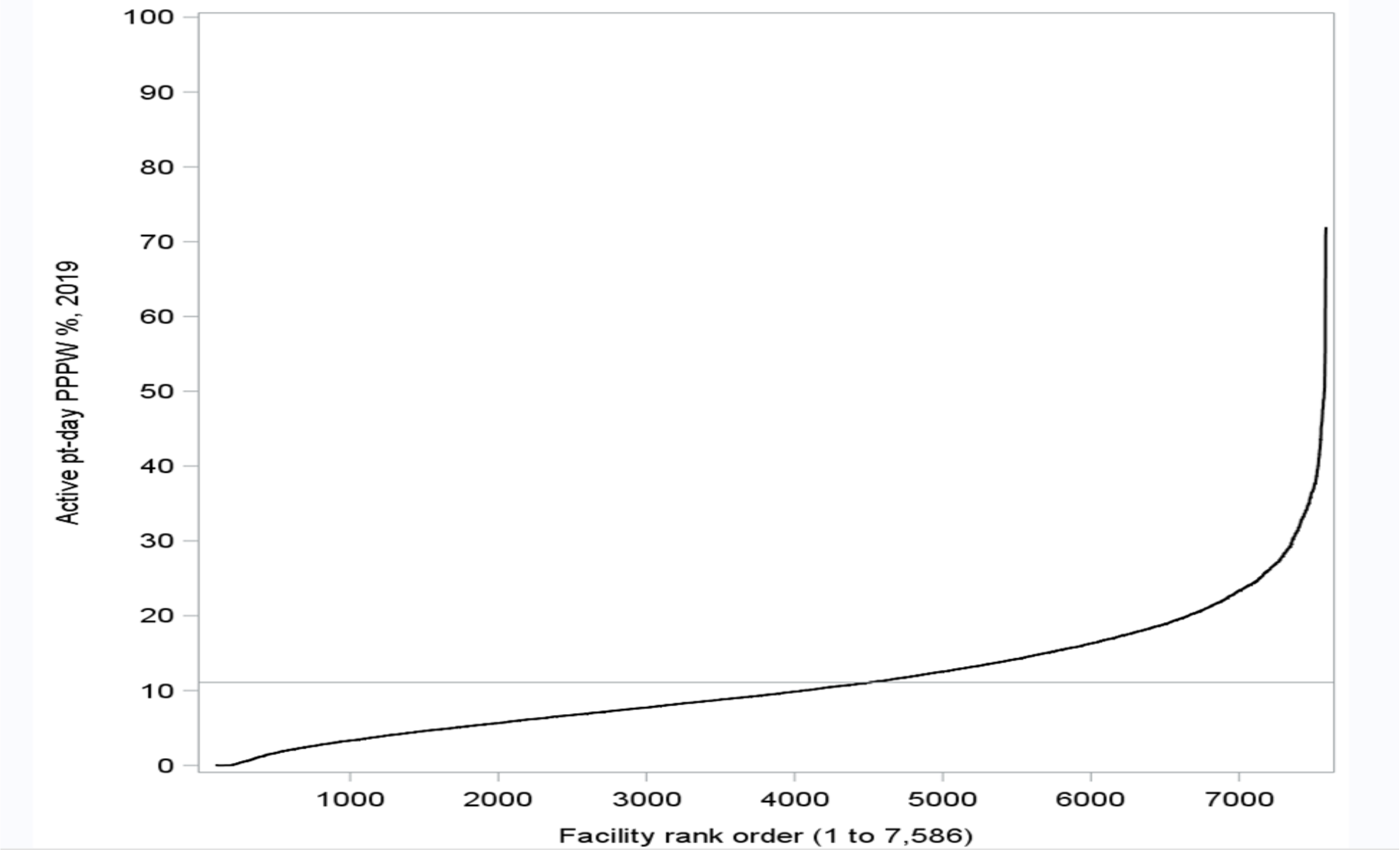
- Measures submitted to NQF but not endorsed:
  - Evidence for benefit of transplant vs evidence for benefit of waitlisting
  - Insufficiently address concerns about benefits vs risks of measures
  - Concerns about insufficient exclusions
  - Concerns about no incorporation of patient preferences

- SWR and PPPW included in public reporting program (DFC)
- PPPW planned for inclusion in QIP

Access to Transplant Measures – Active PPPW prototype

- Maintenance of active status on the waitlist is crucial to achieve ultimate goal of transplantation
- Post new KAS active status may be more relevant
- Specifications similar to PPPW but requiring active status on the waitlist for the numerator

Access to Transplant Measures – APPPW Data



Wrap-up

- Next Meeting, Tuesday, April 27th 2021, 2:00-4:00pm EDT (11:00am-1:00pm PDT)
  - Overview of Topics
  - Public Comment Period

Public Comment

Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel 2021

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Agenda

2:00 pm: Background – Access to Transplant Measures
2:20 pm: Background – Practitioner-level Measures
2:30 pm: Measure Focus - Discussion
3:40 pm: Wrap Up
3:50 pm: Public Comment Period

All times listed are Eastern Daylight Time

Background: Access to Kidney Transplant Measures

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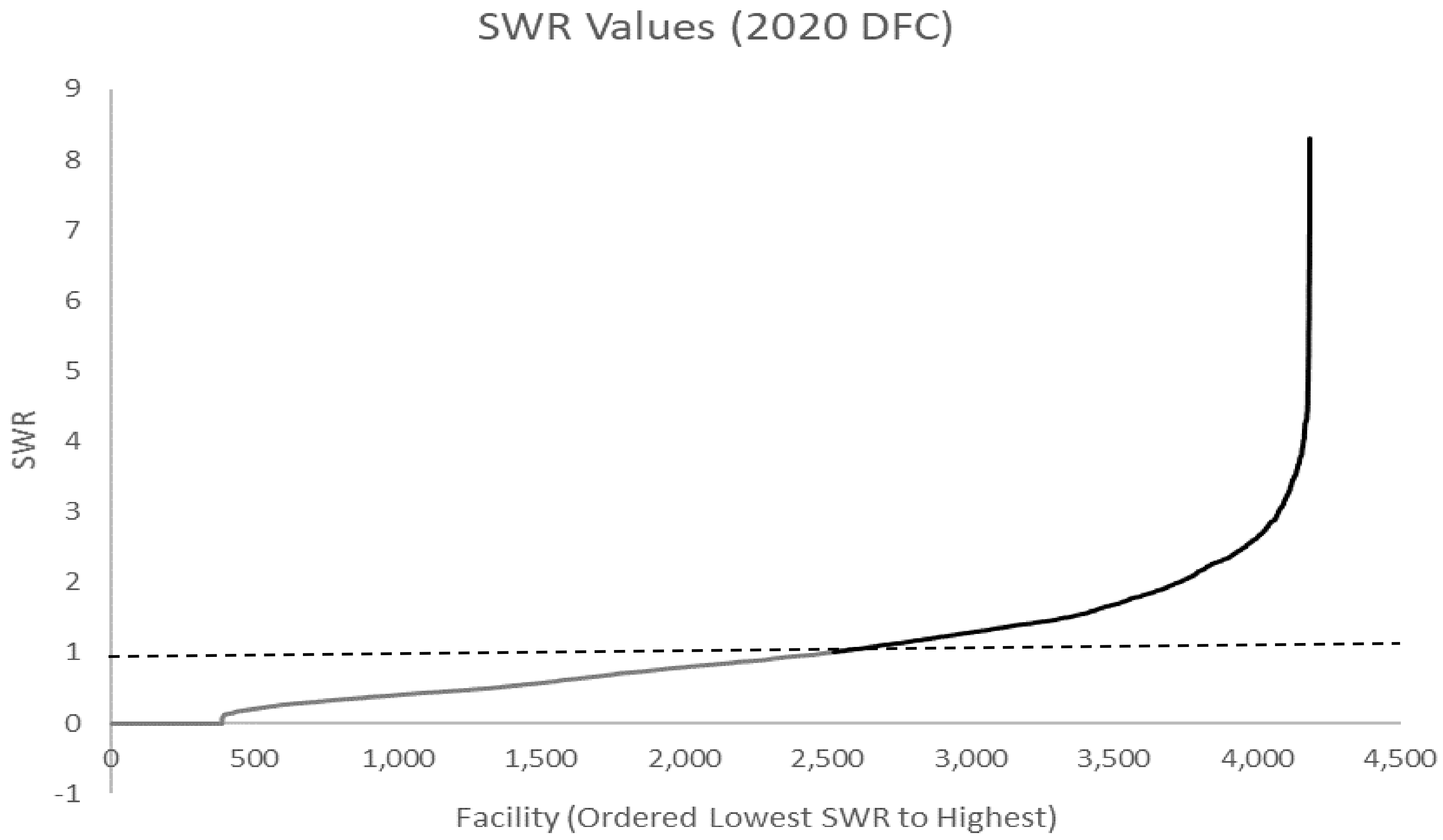

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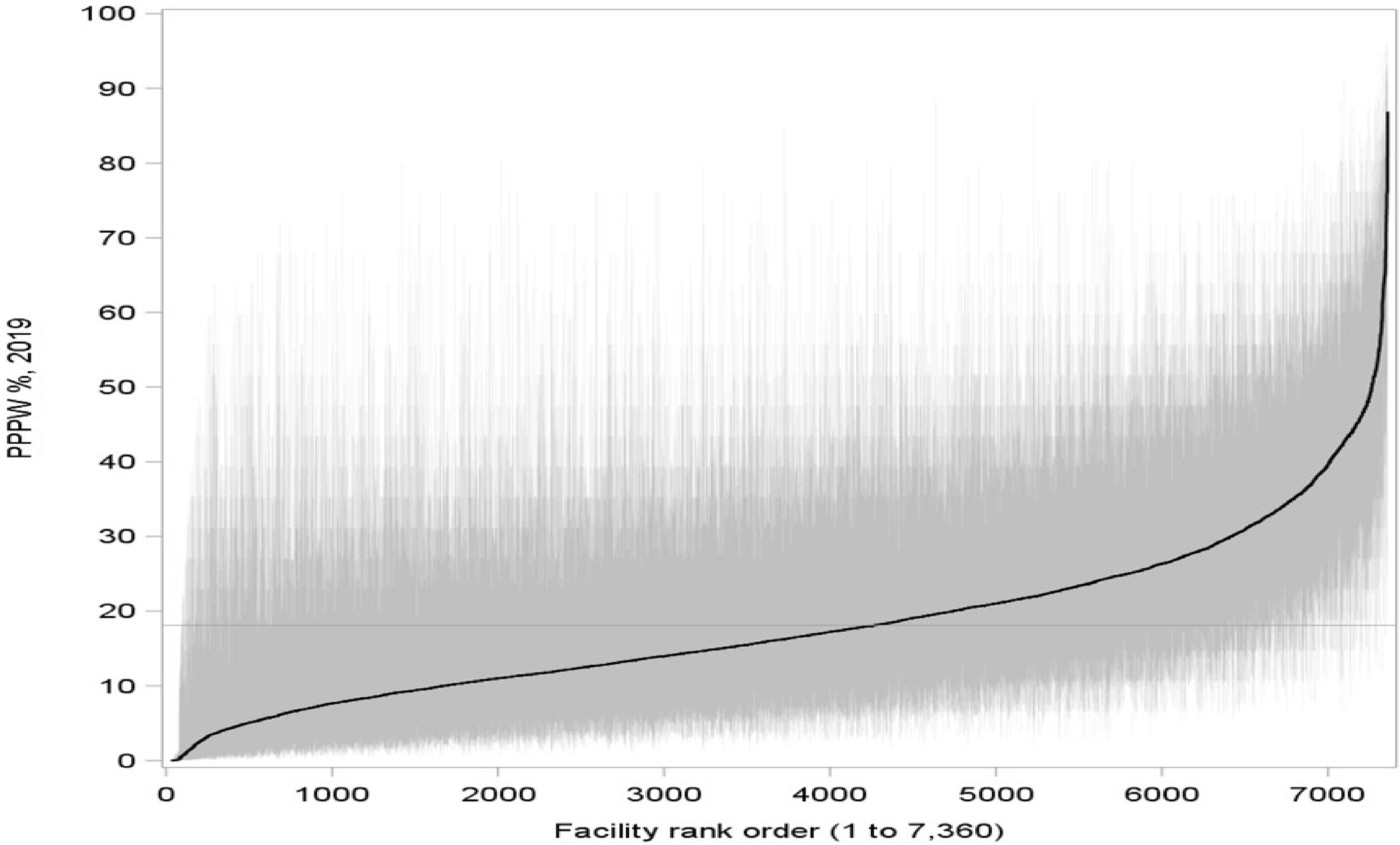

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Access to Transplant Measures - Follow-up

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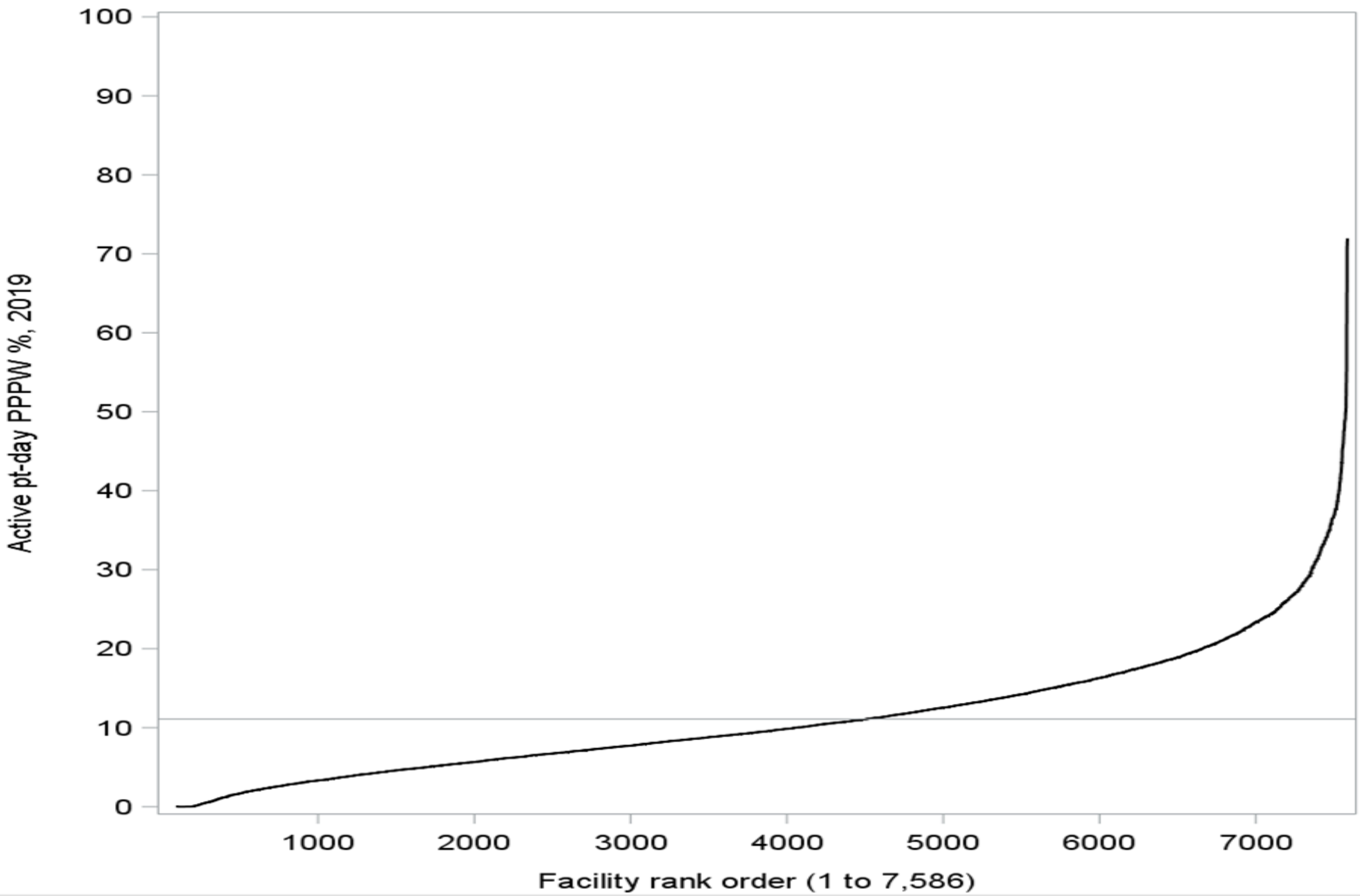

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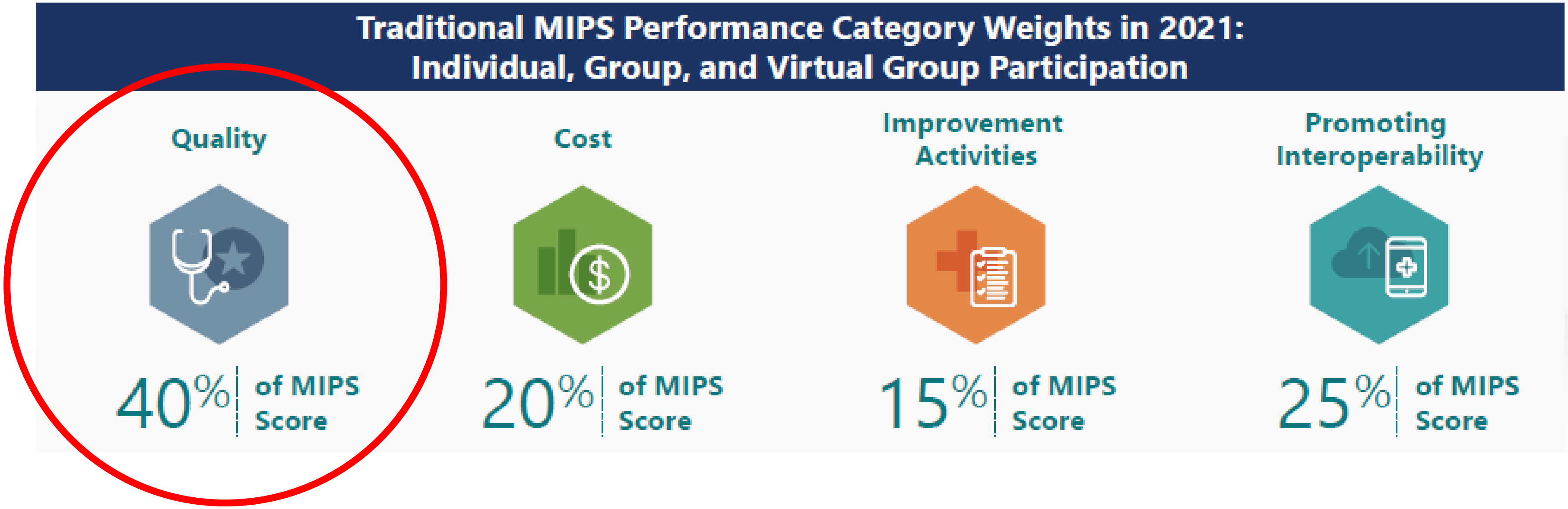
Background: Practitioner-level Measures

Quality Payment Program

- The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 established the Quality Payment Program (replacing the SGR).
- Goal is to reward ‘value’ over volume
- Applies to Medicare practitioners (physicians, but also a variety of other types of health care providers)
- Providers can report as individuals or as groups
- Two main tracks:
  - The Merit-Based Incentive Payment System (MIPS)
  - Alternative Payment Models (APM)

MIPS Scoring



Traditional MIPS Performance Category Weights in 2021: Individual, Group, and Virtual Group Participation

Quality	Cost	Improvement Activities	Promoting Interoperability
40% of MIPS Score	20% of MIPS Score	15% of MIPS Score	25% of MIPS Score

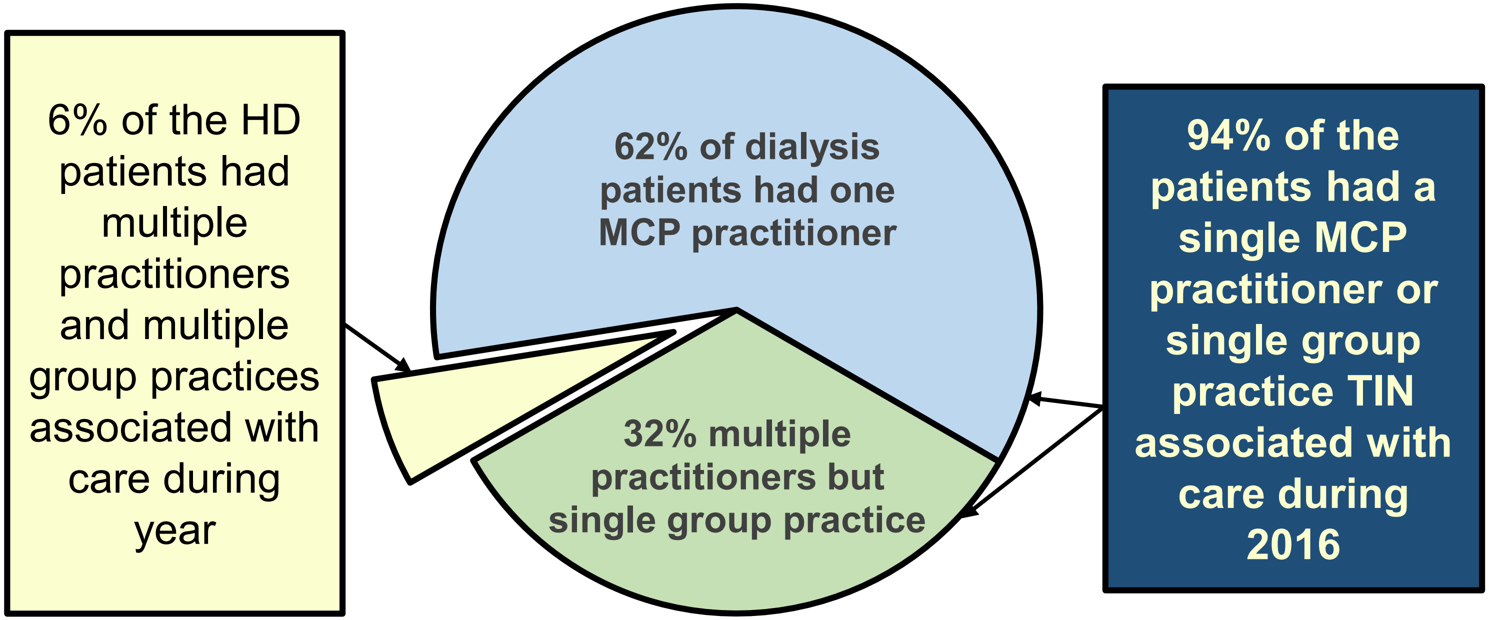
MIPS Quality Measures

- ~200 quality measures to choose from
- Generally 6 measures need to be reported, specialty sets of measures are available
- Variety of data collection mechanisms, many are Medicare Part B claims-based

MIPS Quality Measures - Examples

Measure Title	Description
Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period
Preventive Care and Screening: Influenza Immunization	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization
Pneumococcal Vaccination Status for Older Adults	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine
Functional Outcome Assessment	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies

Attribution of Dialysis Care by MCP Practitioner and Group Practice Identifier (TIN)



6% of the HD patients had multiple practitioners and multiple group practices associated with care during year

62% of dialysis patients had one MCP practitioner

32% multiple practitioners but single group practice

94% of the patients had a single MCP practitioner or single group practice TIN associated with care during 2016

*Requires Medicare claims

Measure Focus Discussion

Measure Evaluation Criteria

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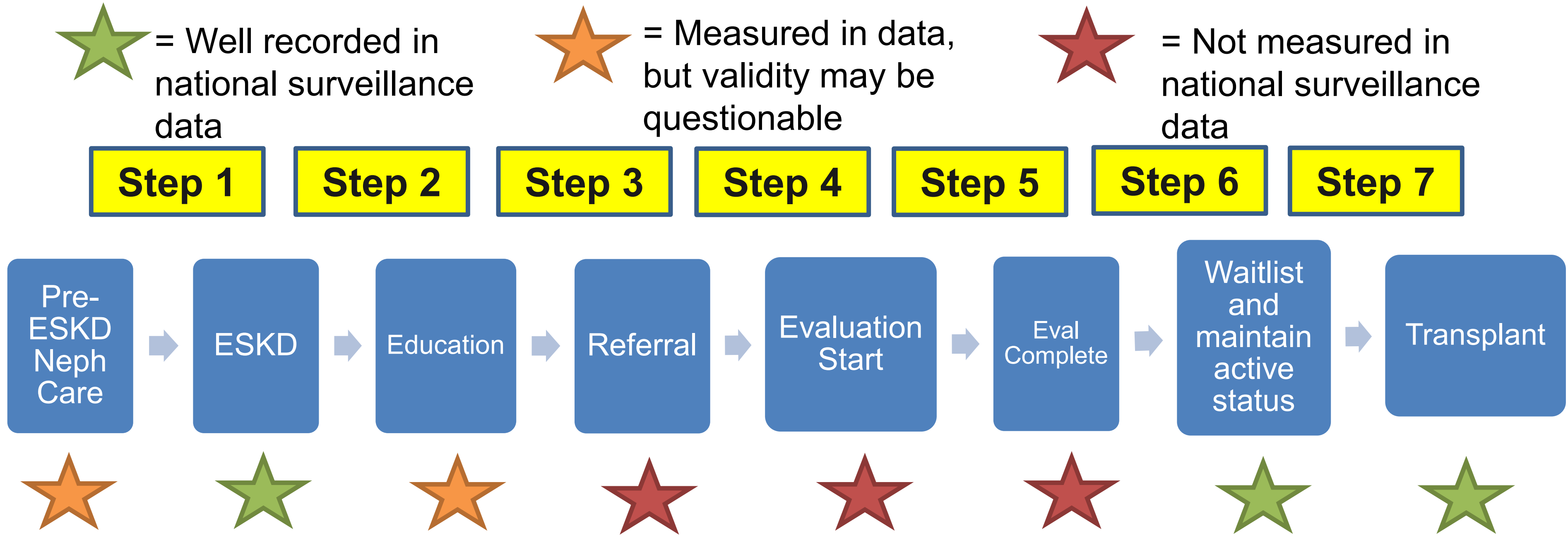
Steps to Kidney Transplant in the U.S.



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Measure Criteria:

Importance Validity/Reliability Feasibility Usability

1. Kim JASN 2012; 23(6)
2. Salter JASN 2014; 25(12)

Wrap-up

- Next Meeting, Tuesday, May 11th 2021, 1:30-3:30 pm EDT (10:30am-12:30pm PDT)
  - Measure Specifications

Public Comment

Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel 2021

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Agenda

1:30 pm: Summary of previous session

1:35 pm: Data Presentation Waitlist and Practitioner Measures

2:00 pm: Practitioner Waitlist Measure Discussion

3:10 pm: Wrap Up

3:20 pm: Public Comment Period

All times listed are Eastern Daylight Time

Summary of Prior Discussion

- Waitlisting Measure, concerns about reliability, adjustment/exclusions and factors beyond dialysis practitioner control (e.g. transplant center behavior/interests)
- Referral Measure (and steps beyond), data availability issues
- Education Measure – strong interest, concerns about how to identify/capture
- Interest in pre-ESRD phase (waitlisting, referral)

Waitlist and Practitioner-level Data

PPPW Facility level reliability

- Reliability assessed by Inter-Unit Reliability (quantifies between vs within facility variance in measure)
- Function to some extent of #facilities, # patients/facility
- Exclude facilities with <11 pts
- IUR=0.80

PPPW Facility Consistency over Time

- Pearson correlation = 0.9 for PPPW in 2018 vs 2019

2018

		Worse	As Expected	Better
2019	Worse	**75**	83	0
	As Expected	92	**6,245**	101
	Better	0	103	**370**

PPPW Facililty Clinical Importance

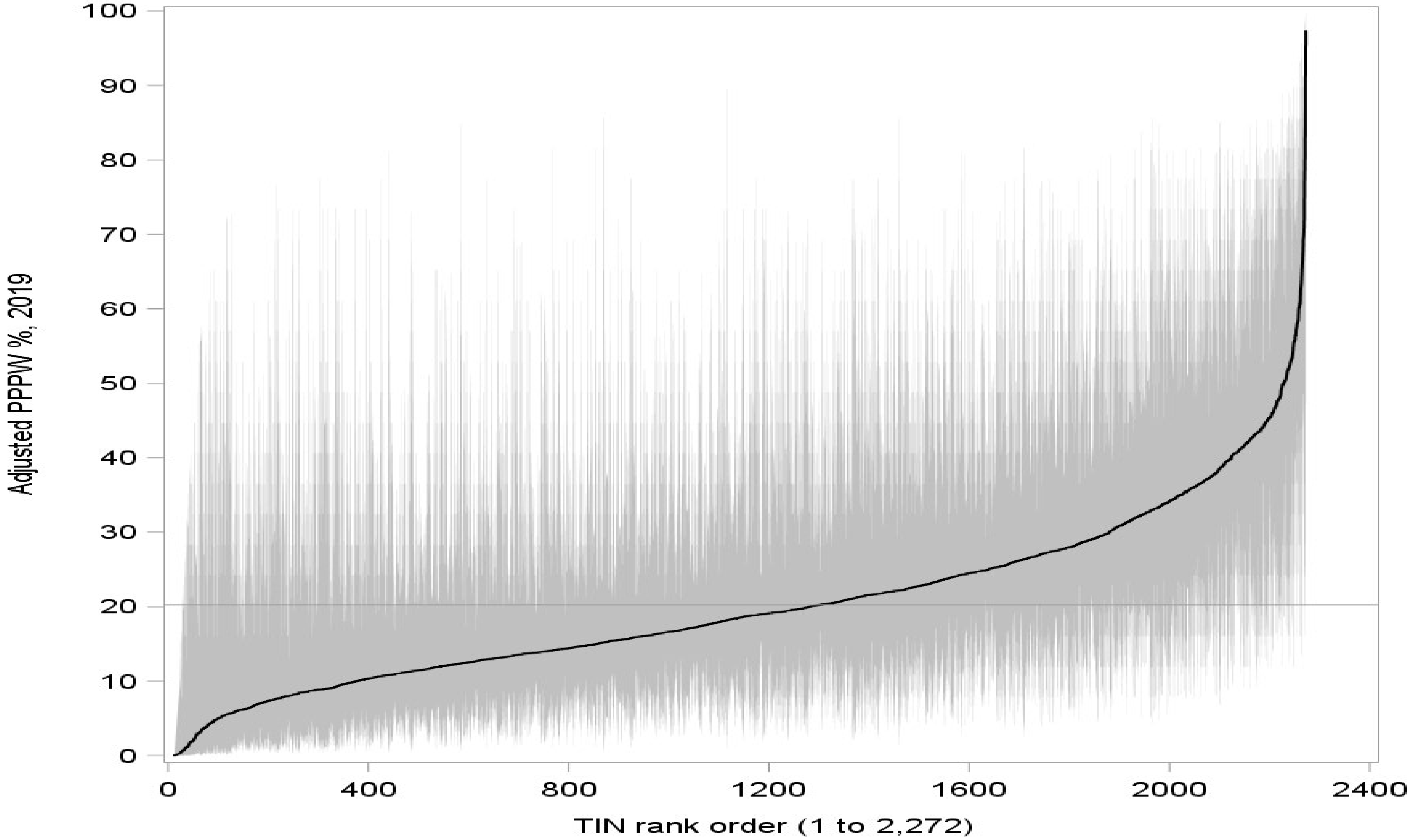
- 2019 As Expected: 15.6%
- 2019 Worse than expected: 0.42%
- 2019 Better than expected: 40.9%

Moving to Practitioner Level

- Attribution based on NPI (individual physician) or TIN (practice) on monthly capitated payment dialysis claims
- *Necessarily limited to patients with Medicare*
- ~2300 eligible TINs for PPPW, median ~60 pts per TIN

- Medicare pts only ~ 280,000 (vs ~460,000 total)
- Medicare PPPW rates slightly higher than overall (18.9% vs 18.0)
- For Facility PPPW correlation for Medicare only pts vs all patients =0.93

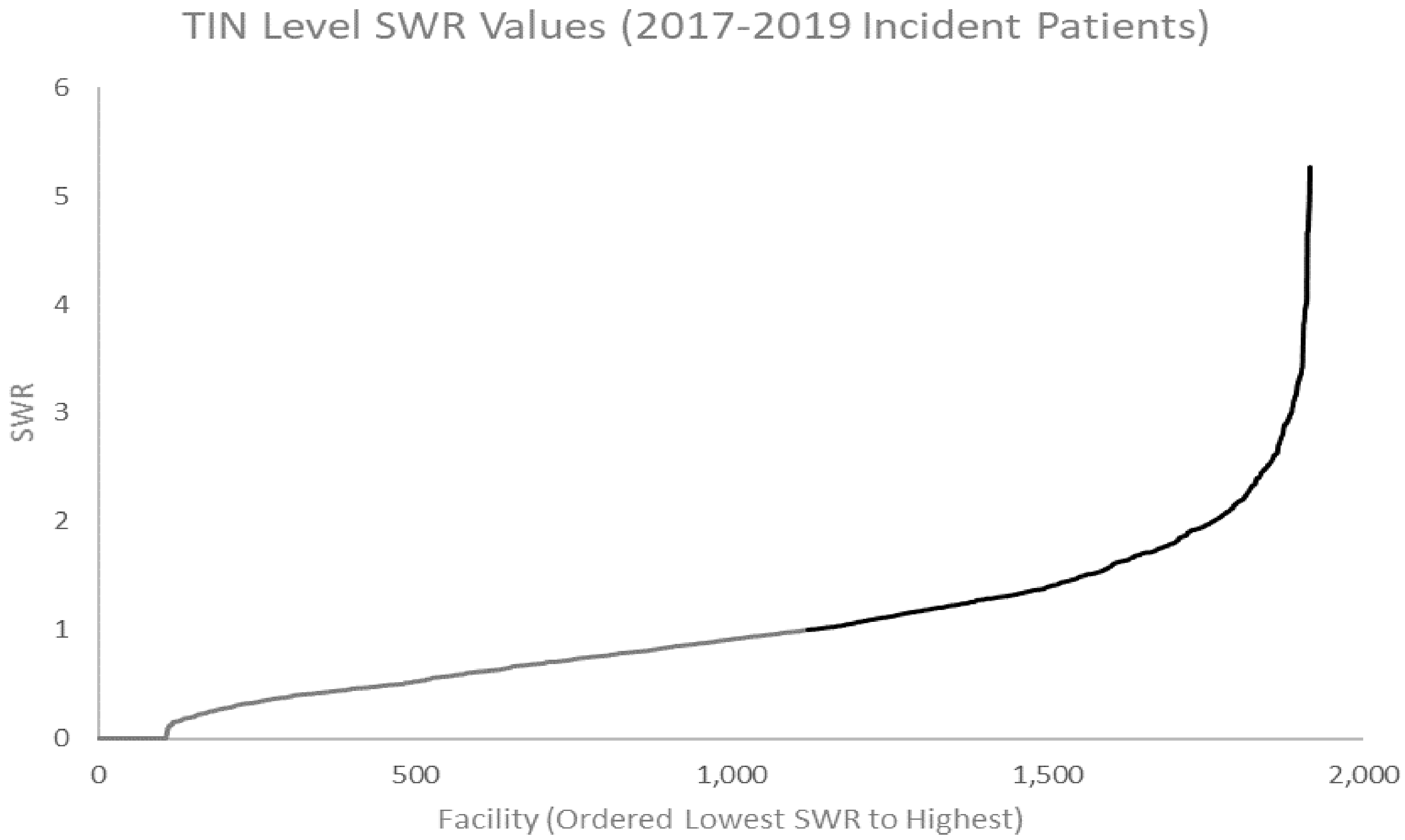
Practitioner level PPPW Variation



SWR Practitioner level measure

- Focuses on first year after dialysis initiation, minority of patients Medicare insured at start
- Practitioner attribution based on 2728 Form, about 75-80% concordance with claims (in those with Medicare)
- 1,914 TINs attributed (2017-2019)
- Correlation for TIN SWR between 2015-2017 vs 2016-2018 =0.86

SWR Practitioner Level Variation



Rationale for dialysis facility waitlist measures

- Acknowledgement of shared responsibility
- Broader view of benefit to population of dialysis patients
- Cautious in choice and extent of adjustment/exclusion to avoid effect of sustaining disparities

Practitioner Waitlist Discussion - Framework

- Appropriateness of a practitioner level waitlist measure
  - Responsibility of dialysis practitioners
  - Performance gap
  - Benefits to dialysis population; Risks?
- Numerator: “outcome” – waitlisting vs active status
- Denominator: Medicare limited? Time since dialysis?
- Exclusions
- Risk Adjustment
- Other issues

Wrap-up

- Next Meeting, Tuesday, May 25th 2021, 2:00-4:00pm EDT (11:00am-1:00pm PDT)
  - Referral Measure

Public Comment

Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel 2021

KIDNEY EPIDEMIOLOGY
AND COST CENTER
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Agenda

2:00 pm:	Transplant Referral Data Collection
2:20 pm:	Standardized Transplant Referral Ratio
2:30 pm:	Practitioner Referral Measure Discussion
3:40 pm:	Wrap Up
3:50 pm:	Public Comment Period

All times listed are Eastern Daylight Time

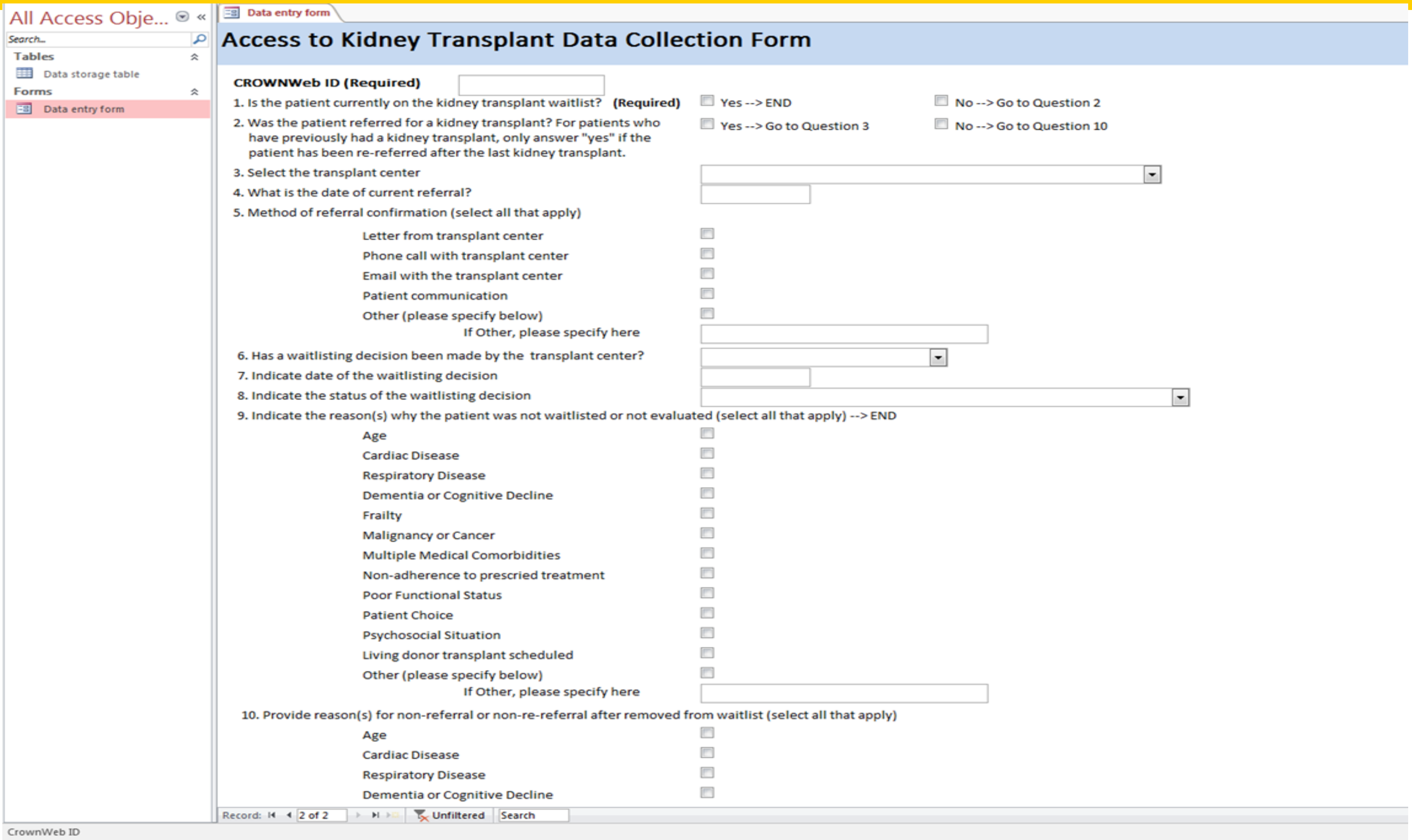
UM-KECC pilot on data collection for referral

- Work done from 2015-2018 under CMS contract
- Initial discussions to develop data collection mechanism using CROWNWeb
- Plan for alpha testing with a small set of dialysis facilities
- Pilot conducted with 2 facilities from one dialysis organization in 2017-2018

UM-KECC pilot on data collection for referral

- Dialysis facilities pulled data from medical records and transmitted in Excel
- Questions sought to determine both new and prior referrals
- Questions sought to determine follow-up result of referral

Data Collection System



Access to Kidney Transplant Data Collection Form

CROWNWeb ID (Required)

1. Is the patient currently on the kidney transplant waitlist? **(Required)** ☐ Yes --> END ☐ No --> Go to Question 2

2. Was the patient referred for a kidney transplant? For patients who have previously had a kidney transplant, only answer "yes" if the patient has been re-referred after the last kidney transplant. ☐ Yes --> Go to Question 3 ☐ No --> Go to Question 10

3. Select the transplant center

4. What is the date of current referral?

5. Method of referral confirmation (select all that apply)

- Letter from transplant center ☐
- Phone call with transplant center ☐
- Email with the transplant center ☐
- Patient communication ☐
- Other (please specify below) ☐

If Other, please specify here

6. Has a waitlisting decision been made by the transplant center?

7. Indicate date of the waitlisting decision

8. Indicate the status of the waitlisting decision

9. Indicate the reason(s) why the patient was not waitlisted or not evaluated (select all that apply) --> END

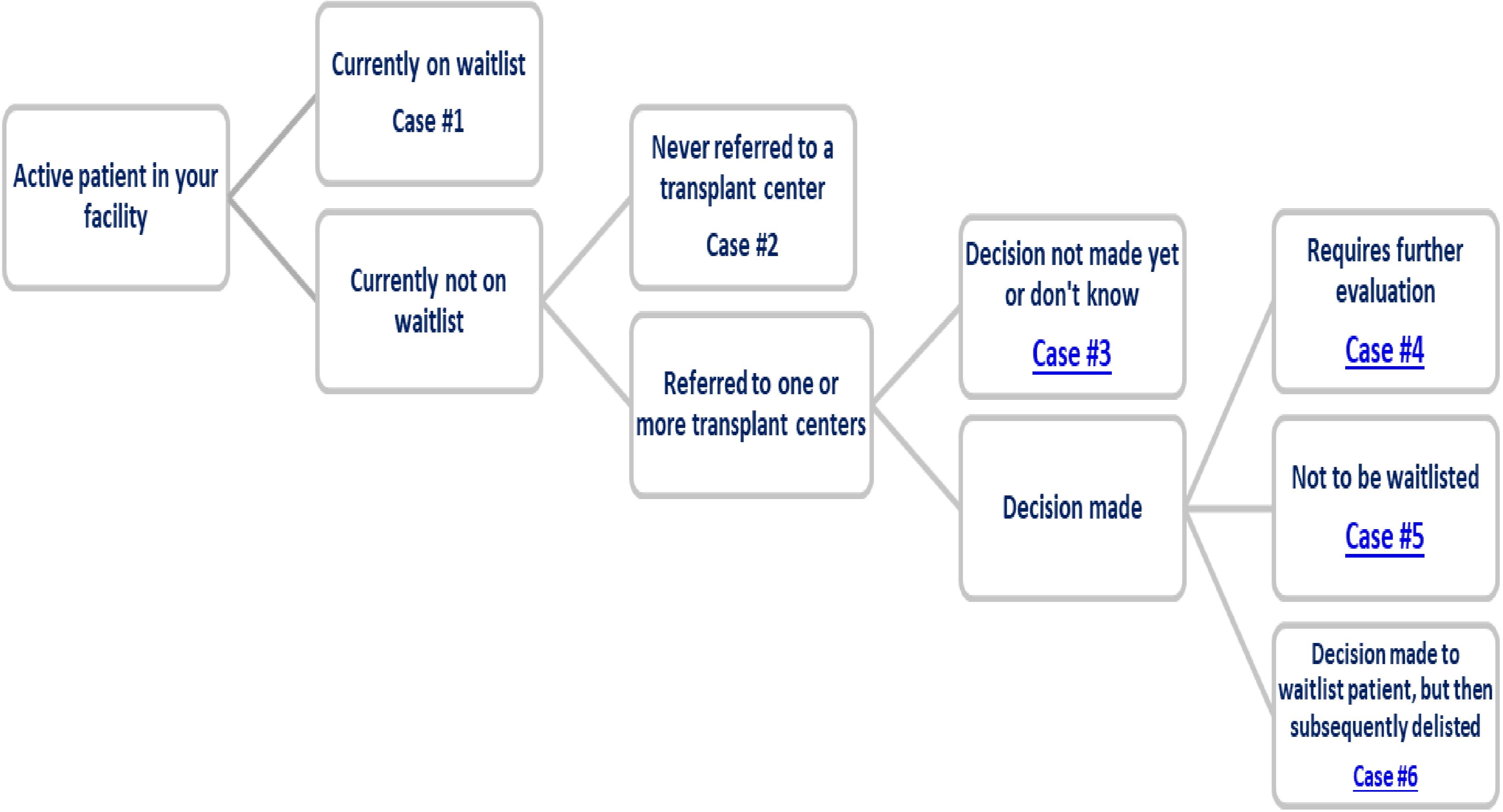
- Age ☐
- Cardiac Disease ☐
- Respiratory Disease ☐
- Dementia or Cognitive Decline ☐
- Frailty ☐
- Malignancy or Cancer ☐
- Multiple Medical Comorbidities ☐
- Non-adherence to prescried treatment ☐
- Poor Functional Status ☐
- Patient Choice ☐
- Psychosocial Situation ☐
- Living donor transplant scheduled ☐
- Other (please specify below) ☐

If Other, please specify here

10. Provide reason(s) for non-referral or non-re-referral after removed from waitlist (select all that apply)

- Age ☐
- Cardiac Disease ☐
- Respiratory Disease ☐
- Dementia or Cognitive Decline ☐

Question Logic



Active patient in your facility

Currently on waitlist

Case #1

Currently not on waitlist

Never referred to a transplant center

Case #2

Referred to one or more transplant centers

Decision not made yet or don't know

Case #3

Decision made

Requires further evaluation

Case #4

Not to be waitlisted

Case #5

Decision made to waitlist patient, but then subsequently delisted

Case #6

Example Questions

Question 2: Was the patient referred for a kidney transplant? For patients who have previously had a kidney transplant, only answer "yes" if the patient has been re-referred after the last kidney transplant.

Question 3: Select transplant center (drop down)

Question 4: Date of referral (estimate if necessary)

Question 5: Method of referral confirmation (letter/phone/email from transplant center; patient communication)

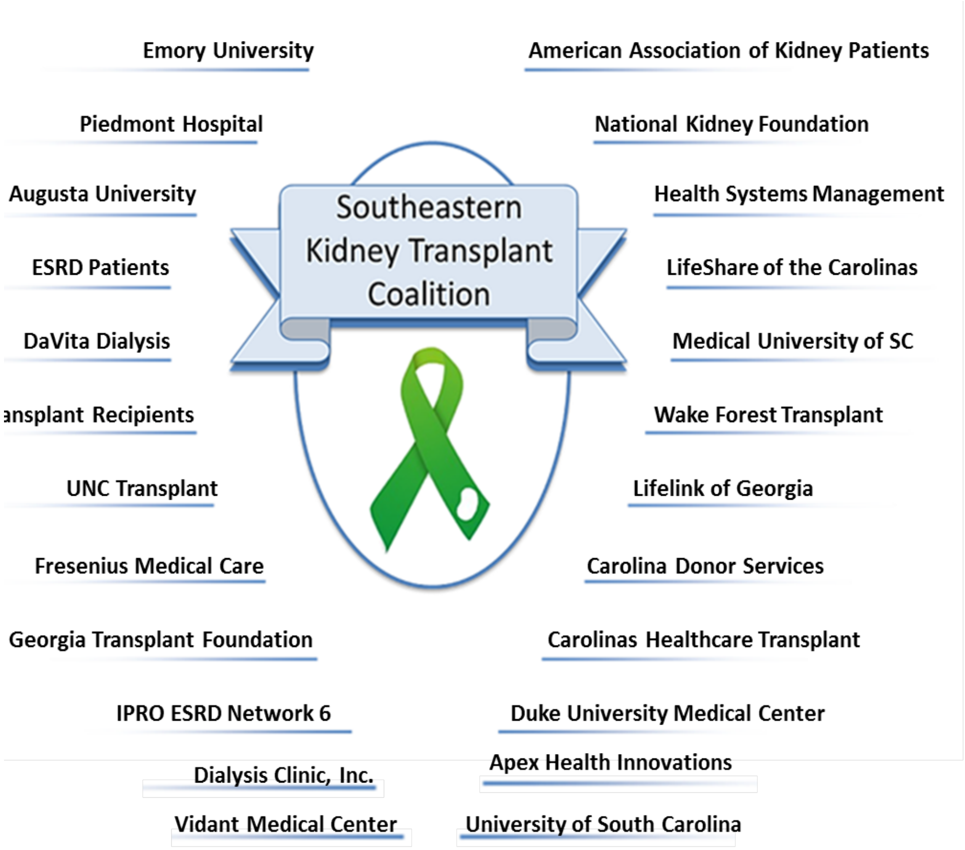
Question 10: Reasons for non-referral (list)

UM-KECC Pilot Summary

- Data collection was feasible in most cases
- Burdensome to obtain historical data, particularly for patients new to facility
- Some scenarios quite complex to adequately capture (e.g. multiple referrals, unclear status of evaluation from transplant center).

Early Transplant Access Registry: Pilot

- Southeastern Kidney Transplant Coalition
  - Grassroots organization formed in 2011
  - Patient, family, and professional membership, ESRD Network
  - Mission: improve access to kidney transplantation and reduce inequities in transplant access
- CMS Statement of Work for ESRD Networks alignment
  - C.4.2 Improve Transplant Coordination – Intent is to promote early referral to transplant, and assist patients and providers to improve referral patterns
  - C.4.2.b. Increase Rates of Patients on a Transplant Waitlist



Southeastern Kidney Transplant Coalition

Emory University

Piedmont Hospital

Augusta University

ESRD Patients

DaVita Dialysis

ansplant Recipients

UNC Transplant

Fresenius Medical Care

Georgia Transplant Foundation

IPRO ESRD Network 6

Dialysis Clinic, Inc.

Vidant Medical Center

American Association of Kidney Patients

National Kidney Foundation

Health Systems Management

LifeShare of the Carolinas

Medical University of SC

Wake Forest Transplant

Lifelink of Georgia

Carolina Donor Services

Carolinas Healthcare Transplant

Duke University Medical Center

Apex Health Innovations

University of South Carolina

Pre-Transplant Data Registry, 2012-2016
Data Collection Methods

Augusta University

Emory University

Piedmont Transplant Institute

Medical University of South Carolina

Duke University

Carolinas Medical Center

UNC Transplant

Vidant Medical Center

Wake Forest Baptist Medical Center

Transplant centers submit patient-level Excel file via a Secured Filed Transfer Protocol

REDCap
Research Electronic Data Capture

ESRD Network 6
Coordinating Center

Patient-Level Pre-Transplant Data Registry – Collected Fields

Patient Name
Patient DOB
Patient SSN
Patient Race
Patient Sex
Patient Address
Patient Insurance

Referred Transplant Center
Preemptive Referral
Dialysis Start Date
Dialysis Facility Name
Dialysis Facility Address
Dialysis Facility CCN

Referral Date
Evaluation Start Date
Evaluation Completion Date
Waitlisting Date
Referring Physician Info
Referring Staff Info

*BOLD indicates required field

Pre-Transplant Data Registry, 2012-2016
Data Collection Methods

ESRD Network *Coordinating Center*

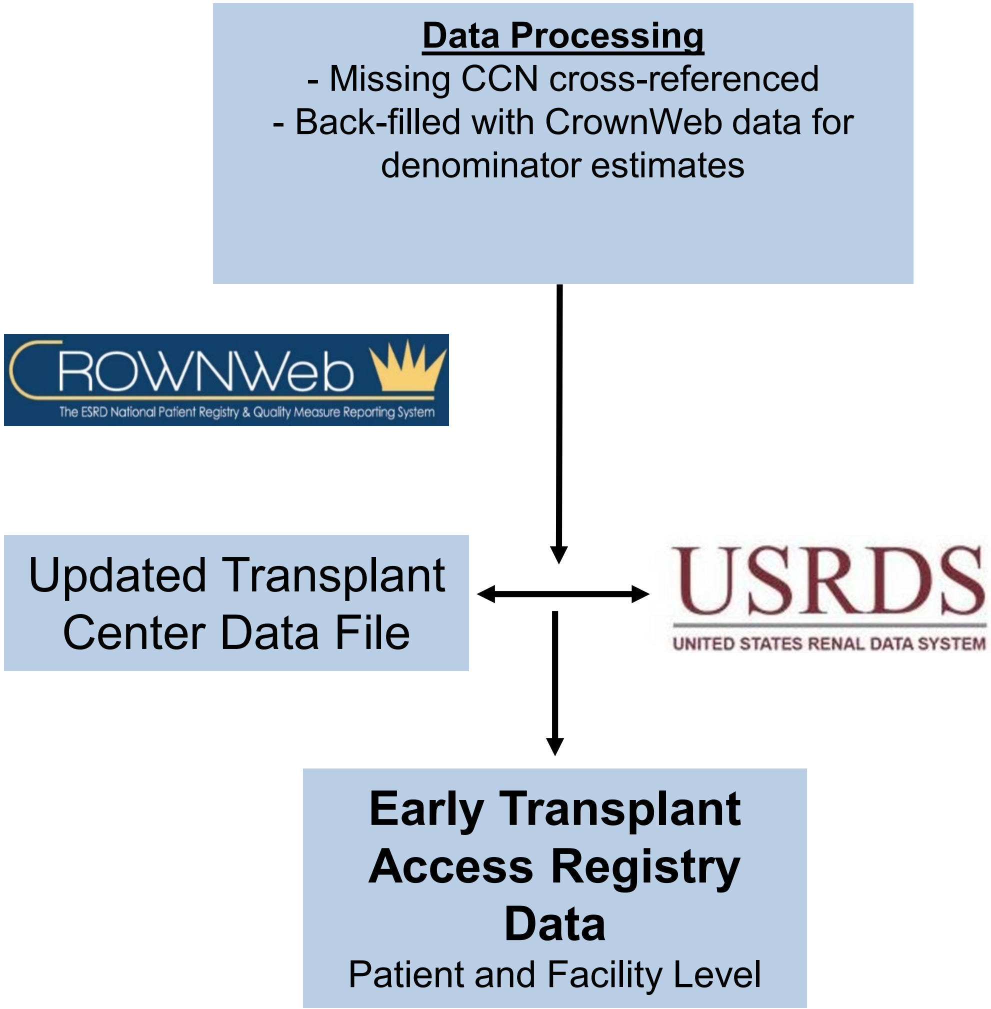
- Receipt of transplant center data file through REDCap

- Perform additional quality checks for:
  - Missing values
  - Field validation errors
  - Incorrect values

- Backfill missing fields with CROWNWeb-supplied data

- Create a data file with selected fields to submit to the United States Data Systems (USRDS) for linkage to national surveillance data

IPRO End-Stage Renal Disease Network of the South Atlantic



Data Processing
- Missing CCN cross-referenced
- Back-filled with CrownWeb data for denominator estimates

Updated Transplant Center Data File

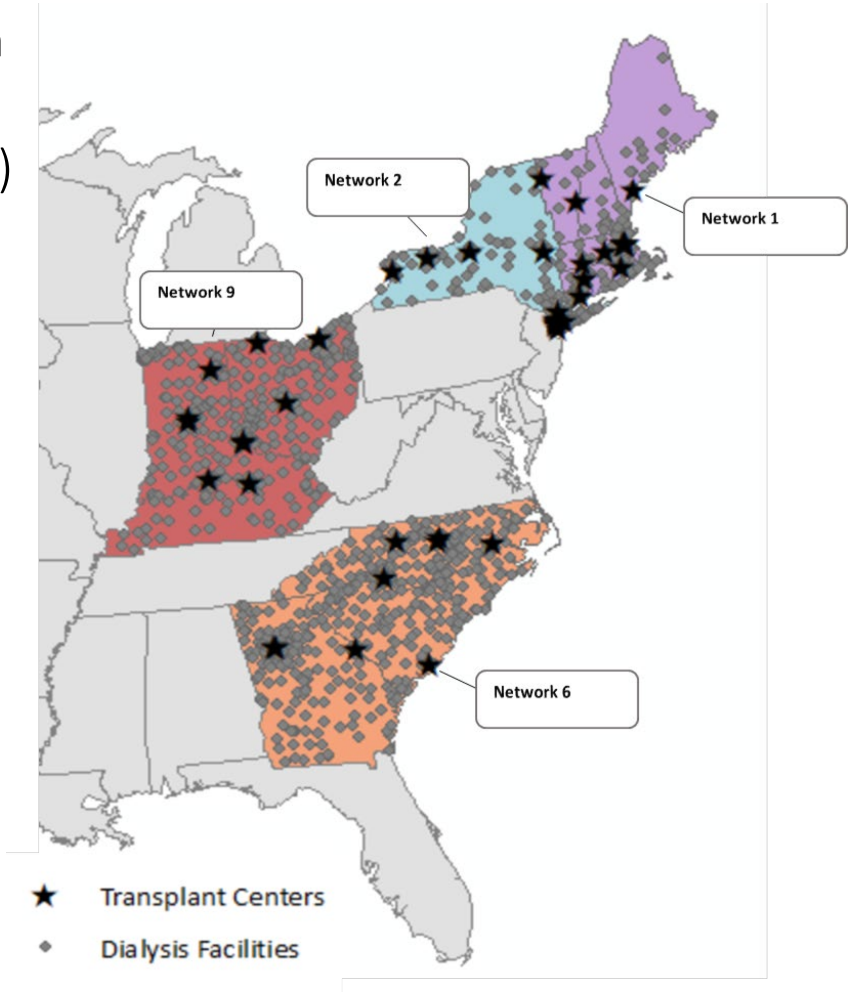
Early Transplant Access Registry Data
Patient and Facility Level

Early Transplant Access Registry: Expansion

- Received funding in 2016 to data collection on early transplant steps to states in End-Stage Renal Disease Network 6 (GA, NC, SC)

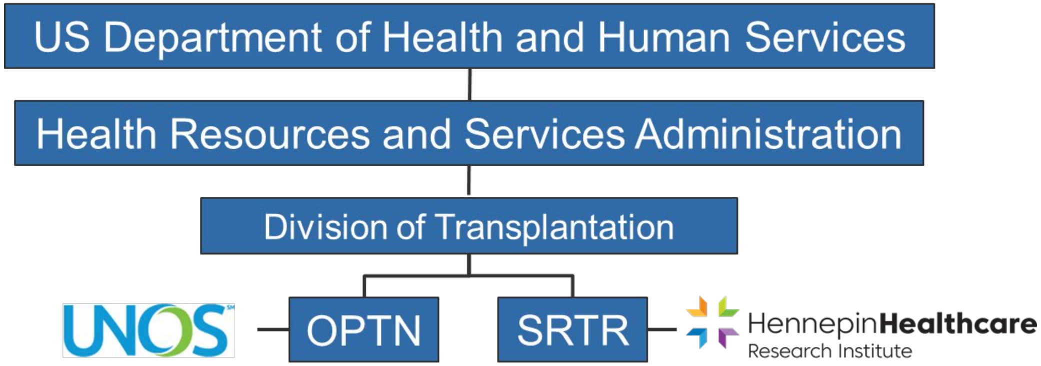
- In 2019, received NIH funding to expand referral and evaluation data collection to three additional ESRD Regions

- Expansion in IPRO Networks: GOAL
  - 48 transplant centers and ~1833 dialysis facilities
  - Current: 28 transplant centers & ~1,000 dialysis facilities
  - Phased approach of data collection



Paul et al. CJASN 2018; 13:282

Other National Updates Related to Referral



US Department of Health and Human Services

Health Resources and Services Administration

Division of Transplantation

- United Network for Organ Sharing (UNOS) co-sponsored project on referral data collection
  - Would require public comment and approval

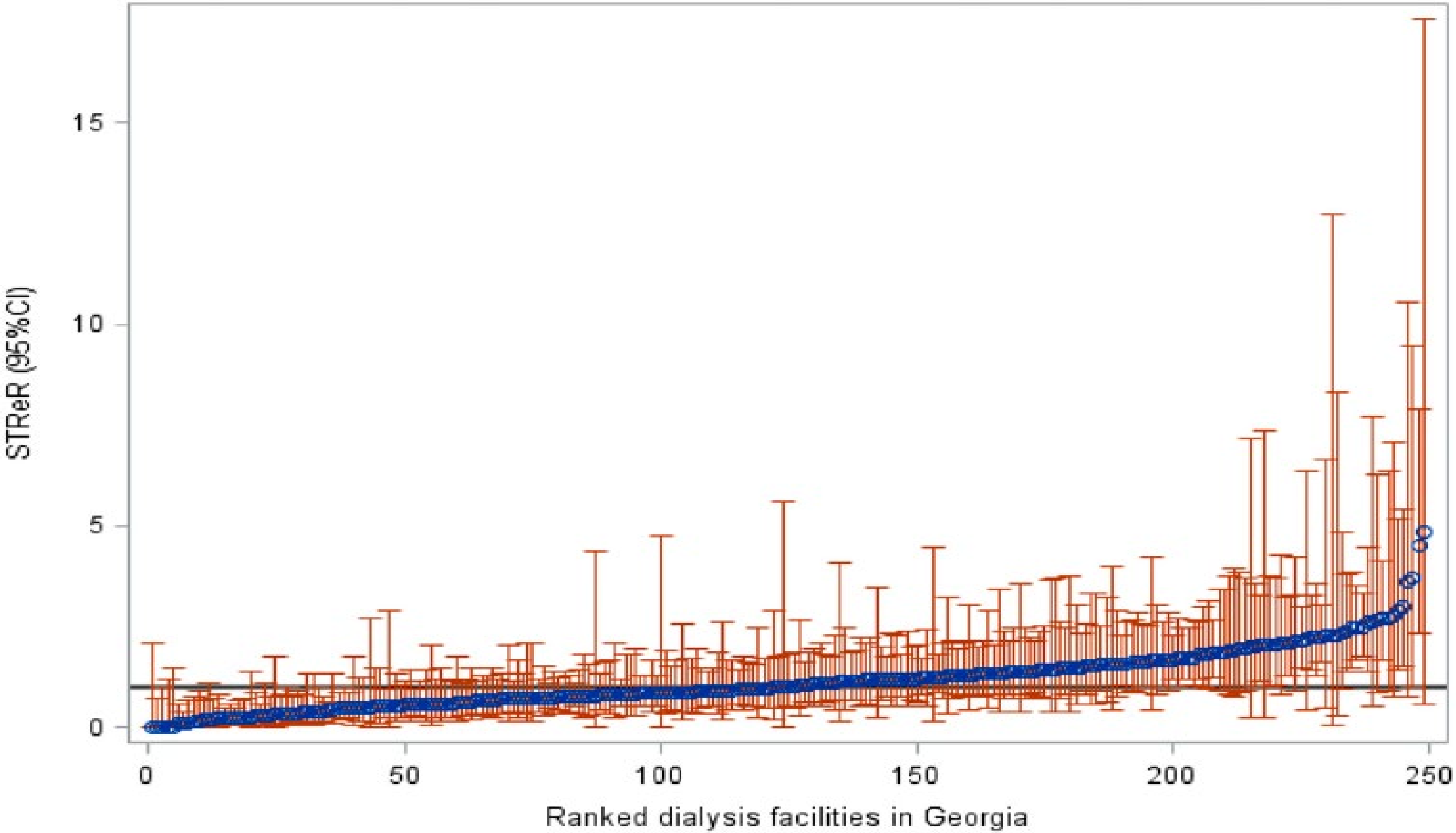
- Scientific Registry of Transplant Recipients (SRTR) Task 5 focus on transplant center quality measures
  - Identify metrics to assess national transplantation system performance and support informed decision-making by critical audiences.

Standardized Transplantation Referral Ratio (STReR)

- Analysis based on 8,308 patients with incident ESRD from 2008-2011 (follow up through 2012), followed at 249 dialysis facilities in Georgia
- Referral for transplantation obtained from transplant centers
- Measured at facility level
- Numerator: Observed no. of first referrals to transplant center within first year of ESRD
- Denominator: Expected no. of first referrals based on Cox model with adjustments as below
- Exclusions: patients above 70 years old; facilities with less than 5 incident ESRD patients per year (72 of 321 excluded)
- Risk Adjustment: age, sex, race, BMI, calendar year of incidence, comorbidities at ESRD start (from Form 2728)
- Other: facility attribution could change within the first year, with time at risk for each facility calculated accordingly

Paul et al. CJASN 2018; 13:282

STReR Facility Variation



Paul et al. CJASN 2018; 13:282

STReR Facility Performance with vs without adjustment

	Model Adjusted for Case Mix			
Model Unadjusted	Better than expected	As Expected	Worse than Expected	Total
Better than Expected	**21 (8)**	5 (2)	0 (0)	26 (10)
As Expected	6 (2)	**185 (74)**	4 (2)	195 (78)
Worse than Expected	0 (0)	1 (0.4)	**27 (11)**	28 (11)
Total	27 (11)	191 (77)	31 (12)	249

Paul et al. CJASN 2018; 13:282

STReR Data Continued

- Reliability: Interunit reliability (IURs) ranged from 22 to 45% from 2008-2011 (overall 33% attributed to between facility variation)
- Validity:
  - Correlation of STReR with transplant evaluation r=0.46 (p<0.001)
  - Correlation of STReR with waitlisting r=0.35 (p<0.001)
  - Correlation of STRer with transplantation r=0.20 (p=0.004)
- Sensitivity Analyses:
  - Correlation of facility STReR with model extending follow-up for referral to two years r=0.96
  - Correlation of facility STReR with model including adjustment for insurance status r=0.98

Paul et al. CJASN 2018; 13:282

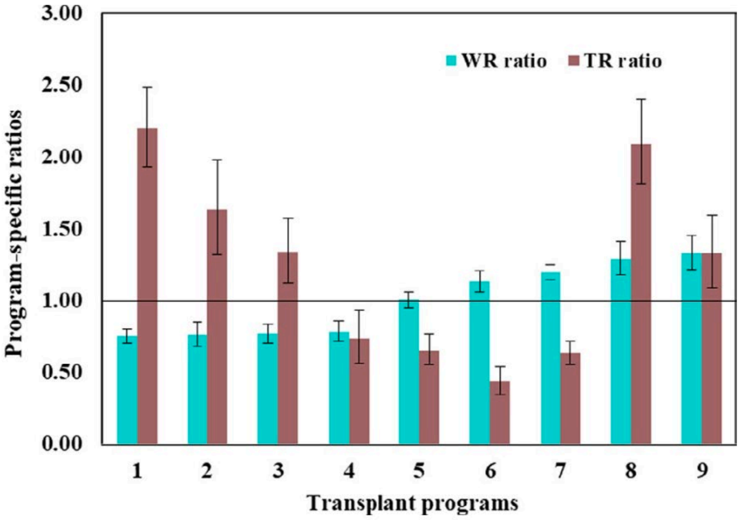
Is referral associated with other quality measures?

Dialysis Facility Quality Measures [1]

- Higher referral was associated with higher % vascular access, informed of transplant options, pre-ESRD nephrology care, and higher levels of waitlisting and transplantation
- Referral was not associated with most other non-transplant quality indicators (e.g., mortality, hospitalization, anemia management, flu vaccination rates, etc).

Transplant Center Quality Measures [2]

- Waitlisting among referred patients vs. Transplant Rate among waitlisted patients for 9 programs
- Measures were not correlated ($r = -.15$, 95% CI, −0.83 to 0.57)



1. Plantinga LC *AJKD 2017 69(2)* *2. Paul S AJT 2021 21 (1)*

Practitioner Referral Measure Discussion - Framework

- Appropriateness of a practitioner level waitlist measure
  - Responsibility of dialysis practitioners
  - Performance gap
  - Benefits to dialysis population; Risks?
- Data Collection
- Numerator: Referral timing (first year only or beyond)
- Denominator: Medicare limited?
- Exclusions
- Risk Adjustment

Wrap-up

- Next Meeting, June 8th, 2021, 1:30-3:30pm EDT (10:30am-12:30pm PDT)
  - Referral Measure

Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel 2021

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Agenda

1:00 pm: Meetings Re-cap

1:05 pm: Measure Evaluation Criteria Review

1:15 pm: Overview of Practitioner Waitlist Measures

1:30 pm: Discussion of Measure Specifications

2:40 pm: Wrap Up

2:50 pm: Public Comment Period

All times listed are Eastern Daylight Time

Meetings Re-Cap

- Practitioner Waitlisting Measures Discussion Points
  - Concern for factors outside of practitioner control
  - Transplant center decision-making
  - Patient medical factors
  - Patient social factors
  - For SWR, concern about focus on first year only
  - Overall waitlisting vs active status on the waitlist

- Practitioner Referral Measure Discussion Points
  - Under practitioner control
  - Concern it is only start of the process
  - Data availability
  - Quality of referral (ie. patients properly educated prior to referral?)

Meetings Re-Cap

- Strong interest in pre-ESRD phase of care
- Importance of education

Measure Evaluation Criteria Review

- Importance to Measure and Report
  - Evidence (link from referral/waitlisting to transplant/good outcomes
  - Performance Gap (ample data to support)
- Scientific Acceptability
  - Reliability (will show IURs)
  - Validity (mostly about appropriate risk adjustments and exclusions – to capture quality of practitioner performance)
- Feasibility
  - Measures necessarily limited by available data
- Usability
  - Measure results are actionable to help improve performance
- Harmonization
  - Justification needed if more than one measure in a given area

Overview of Proposed Practitioner Waitlist Measures

- Structure/Focus – 4 Measures
  - Standardized Waitlist Ratio (SWR) First Year (aggregated across 3 years)
  - Standardized Waitlist Ratio First Year and Beyond (accounts for patient transfers and includes adjustment for dialysis vintage)
  - PPPW
  - Active PPPW

Overview of Proposed Practitioner Waitlist Measures

- Medicare vs All patients
- Beyond first year of ESRD, measures will need to be Medicare only for practitioner attribution (and comorbidity adjustment)
- ~60% of prevalent dialysis population is Medicare insured; correlation for facility PPPW between Medicare and All patients =0.93
- Within first year, practitioner attribution (and comorbidity adjustment) can be done for all patients

Overview of Proposed Practitioner Waitlist Measures

- Practitioner (dialysis physician) individual (NPI) vs group practice level (TIN)

	IUR		
	Facility	TIN	NPI
SWR	0.56	0.60	0.36
PPPW	0.80	0.86	0.71
APPW	0.75	0.81	0.64

Overview of Proposed Practitioner Waitlist Measures

- Exclusions: Age 75 years or older, nursing home residence, hospice
- Medical Risk (Comorbidity) Adjustment
- Social Risk Adjustment
- Transplant center adjustment?

Background: Comorbidity Adjustment Strategy

- Two main sources of comorbidity data: Form 2728 (most relevant proximate to ESRD) and claims (requires Medicare)
- Claims based comorbidity adjustment requires a process for synthesis of diagnoses and selection
- One example is the Clinical Classification System (CCS), developed by the AHRQ and includes 282 groupings based on ICD codes
  - Cancer of the lung
  - Opioid dependence
  - Dementia
  - Below knee amputation status

Background: Comorbidity Adjustment Strategy

- Rationale for comorbidity adjustment is to account for reasons patients may appropriately not be waitlisted for medical reasons
- We plan to use Form 2728 comorbidities, and Medicare claims categorized by CCS
- Selection strategy for inclusion in adjustment will be factors most predictive of short term (one year) mortality
- Prefer to avoid exclusions given few truly absolute contraindications to kidney transplantation

Background: Comorbidity Adjustment Strategy

	SWR Adjusted for Comorbidity			
SWR Unadjusted	Better than expected	As Expected	Worse than Expected	Total
Better than Expected	**104**	11	0	115
As Expected	16	**1243**	20	1279
Worse than Expected	0	22	**85**	107
Total	120	1276	105	1501

TIN Level SWR, correlation between two models =0.97

Discussion: Medical Risk Adjustment/Exclusions

- Concerns about proposed medical risk adjustment strategy?
- Additional/alternate suggestions for comorbidity adjustment?
- Are suggested exclusions appropriate:
  - Age 75 years or older
  - Nursing home residence
  - Hospice

Background: Social Risk Adjustment

- Area of immense current interest, and subject of ongoing deliberations in quality measurement space

- “Social Risk Factor” definition: social conditions that may influence health outcomes as much as—or more than—medical care does, including socioeconomic position/status (e.g., income, education, and occupation); race/ethnicity and cultural context; gender; social relationships; and residential and community context, as well as health literacy.

- These factors must possess a conceptual and empirical relationship to healthcare outcomes of interest, preceding care delivery, and refrain from being a consequence of the quality of care or something the provider can manipulate.

Background: Social Risk Adjustment

- Rationale for social risk adjustment is to potentially avoid penalizing providers who disproportionately care for disadvantaged populations
- Rationale against social risk adjustment is to potentially avoid sustaining existing disparities
- Decision can be based on both theoretical/conceptual considerations as well as empirical data (i.e. no need for adjustment if it has little impact on measure performance)
- Limited data available for adjustment:
  - Race/ethnicity
  - Sex
  - Insurance (e.g. dual Medicare/Medicaid eligibility)
  - Place of residence factors – eg. Area Deprivation Index

Background: Social Risk Adjustment

	SWR Adjusted for Dual Eligibility			
SWR Unadjusted	Better than expected	As Expected	Worse than Expected	Total
Better than Expected	**117**	3	0	120
As Expected	6	**1282**	8	1296
Worse than Expected	0	7	**98**	105
Total	123	1292	106	1521

TIN Level SWR, correlation between two models =0.99

Background: Social Risk Adjustment

	PPPW Adjusted for Dual Eligibility			
PPW Unadjusted for D.E.	Better than expected	As Expected	Worse than Expected	Total
Better than Expected	**145**	15	0	160
As Expected	31	**1933**	19	1296
Worse than Expected	0	14	**115**	129
Total	176	1962	134	2644

TIN Level PPPW, correlation between two models =0.99

Discussion: Social Risk Adjustment

- Appropriate to adjust for social risk in this context?
- Which factors (bearing in mind data availability limitations)?

Discussion: Patient Preference Exclusion?

- No current data collection mechanism available
- Most medically suitable candidates stand to gain substantial benefit from transplantation
- Patient feelings about transplantation highly influenced by how information/education is presented

Background: Transplant center adjustment

- Challenging and complex to implement
- Attribution of patients to transplant center may be accomplished through zip code of residence (ie. which transplant centers predominantly have waitlisted patients from a given zip code)
- Can include an adjustment for transplant center (e.g. as a random effect) or specific characteristics of transplant center (e.g. transplant rates)
- This approach may account in part for factors outside of dialysis practitioner control that affect waitlisting
- Have used similar approach to adjust for hospital effect for dialysis facility standardized readmission ratio measure

Discussion: Transplant Center Adjustment

- Questions or concerns about this approach?
- Would such an adjustment allay concerns about transplant center factors beyond dialysis practitioner control?

Discussion: Waitlist Measure Structure/Focus

- Which of the following measures are preferred?
  - First year SWR
  - SWR All Years
  - PPPW
  - Active PPPW

Discussion: Appropriateness of Practitioner Waitlist Measure

- Based on proposed measure specifications and discussions, how do you feel about a practitioner waitlisting measure?
- Would such a measure potentially improve access to kidney transplantation?
- Do you have concerns about negative consequences of implementation of such a measure?
- Do you think the benefits to patients outweigh the risks?

Wrap-up

- Next Meeting, Thursday, June 17th 2021, 2:00-4:00pm EDT (11:00am-1:00pm PDT)
  - Follow-up waitlist measure discussion
  - Referral measure discussion

Public Comment

Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel 2021

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Agenda

2:00 pm: Meeting Re-cap and Follow-up

2:05 pm: Waitlist Measure Discussion

3:00 pm: Referral Measure Discussion

3:40 pm: Wrap Up

3:50 pm: Public Comment Period

All times listed are Eastern Daylight Time

Meeting Re-Cap and Follow-up

- Attribution at Group Practice (TIN) level
- Focus on Medicare ESRD population
- Comorbidity adjustments vs exclusions
- ETC model exclusions
- ICD10 SDOH codes

Discussion: Social Risk Adjustment

- Appropriate to adjust for social risk in this context?
- Which factors (bearing in mind data availability limitations)?

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- Would such a measure potentially improve access to kidney transplantation?
- Do you have concerns about negative consequences of implementation of such a measure?
- Do you think the benefits to patients outweigh the risks?

Overview of Practitioner Referral Measure

- Structured similarly to SWR, with focus on new referrals
- Can include first year and beyond
- Similar adjustments/exclusions to waitlisting measures?

Discussion: Referral Measures

- Data Elements needed
  - Date of first referral
  - Pending referral decision (e.g. referred in prior year but no decision yet)
  - Collection of data on reasons for non-referral?

- Any modifications needed for adjustment/exclusion strategy from waitlist measures?

- Overall appropriateness of a practitioner level referral measure

Wrap-up

- Next Meeting, Tuesday, June 22 2021, 2:00-4:00pm EDT (11:00am-1:00pm PDT)

Public Comment

Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel 2021

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Agenda

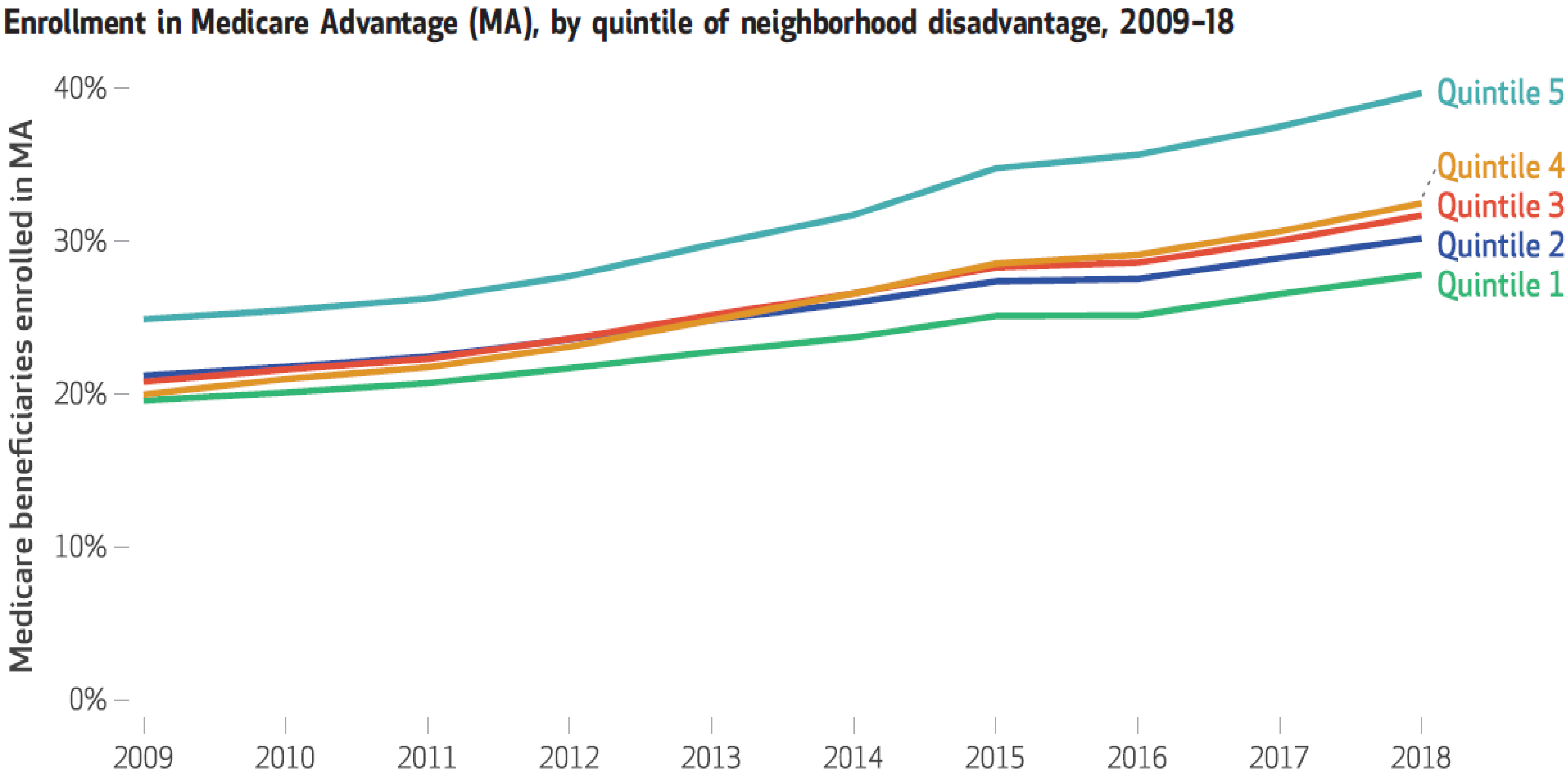
2:00 pm:	Background: Medicare Advantage
2:20 pm:	Referral Measure Discussion
3:05 pm:	Waitlist Measure Discussion
3:30 pm:	Feedback on assessing transplant education
3:40 pm:	Wrap Up
3:50 pm:	Public Comment Period

All times listed are Eastern Daylight Time

Background: Medicare Advantage

- Medicare Advantage (Part C) is an “all in one” plan, covering what Parts A, B, D would cover plus potentially other benefits
- Administered by approved private companies with which Medicare contracts to deliver the services
- More restrictive – e.g. must see in network providers
- Steady increase in growth of MA enrollees as percentage of total Medicare population (about a third)

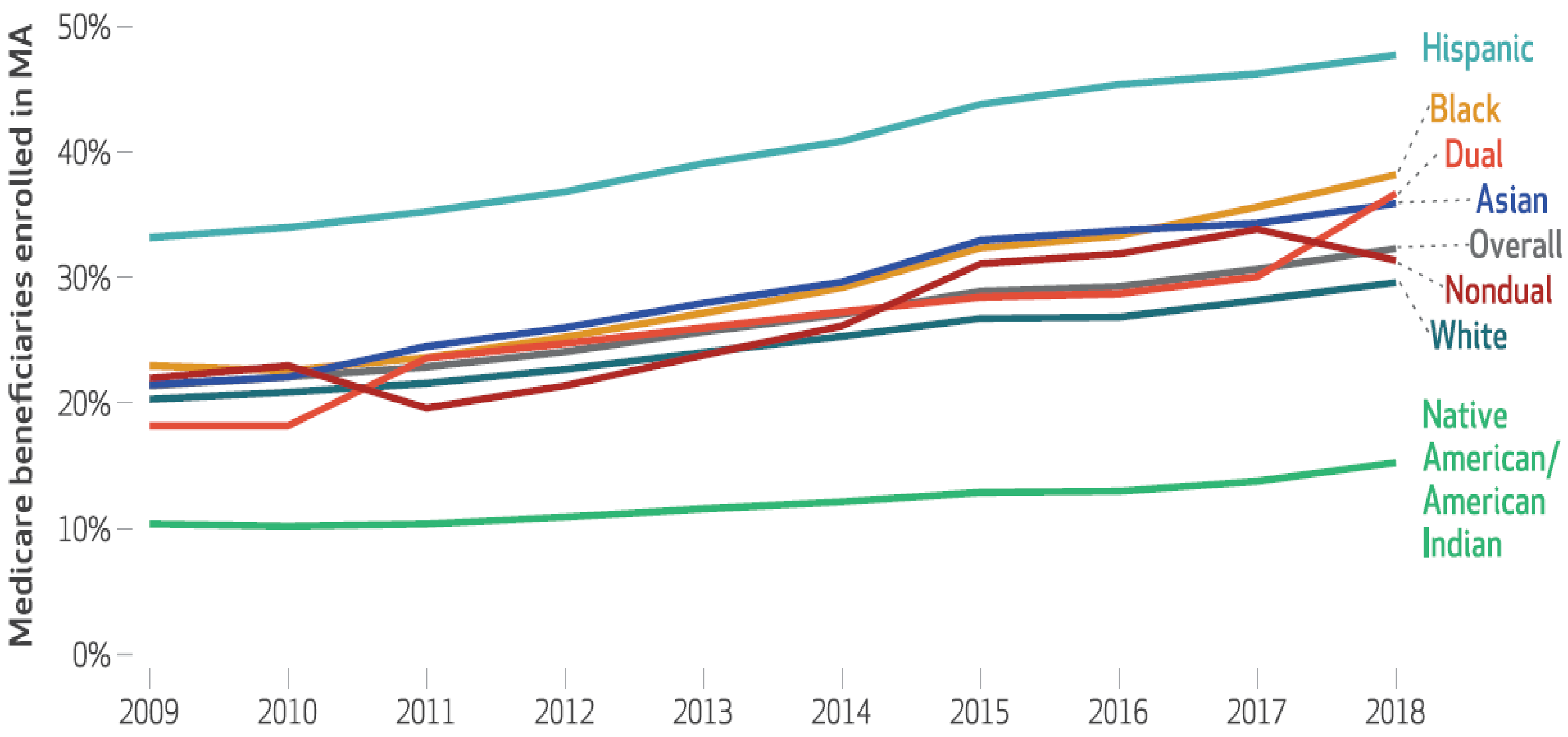
Background: Medicare Advantage



Meyers et al, Health Affairs 2021;945

Background: Medicare Advantage

Enrollment in Medicare Advantage (MA), by race/ethnicity and dual enrollment status, 2009-18



Meyers et al, Health Affairs 2021;945

Background: Medicare Advantage

- Enrollment into MA for ESRD patients until recently more restricted
- As of Oct 2020, ~28% of Medicare dialysis and ~21.8% of all dialysis patients had MA
- CURES act removed restrictions for MA enrollment for dialysis patients as of January 2021
- Industry consultants estimate 60% growth in MA ESRD enrollment through 2026, so could represent nearly half of Medicare dialysis patients

Background: Medicare Advantage

- Data on MA services is available as “encounter data”
- Similar to claims but some differences
- Submission process not same as FFS claims submission standards, and variable due to varying contractors involved
- Government reports from MedPAC and GAO raise concerns about validity and completeness of data
- Additional development work would be needed but improvement in data reporting appears to be a priority
- Quality measures do exist for MA plans

Summary

- Medicare FFS dialysis population likely to continue be a substantial and important group over the next several years and beyond
- Practitioner performance within Medicare FFS patient panel still likely to be reflective of practitioner quality
- Risk adjustments should help mitigate impact of shifting of patients from FFS to MA plans
- Quality measures developed are not static, will be periodically reviewed and can be updated for relevance as patterns of care shift
- CMS perspective

Glied S, J Health Econ 2002:337; Meyers et al JAMA Network Open 2019

Overview of Practitioner Referral Measure

- Structured similarly to SWR, with focus on new referrals
- Can include first year and beyond
- Similar adjustments/exclusions to waitlisting measures?

Discussion: Referral Measures

- Data Elements needed
  - Date of first referral
  - Pending referral decision (e.g. referred in prior year but no decision yet)
  - Collection of data on reasons for non-referral?
- Any modifications needed for adjustment/exclusion strategy from waitlist measures?
- Overall appropriateness of a practitioner level referral measure

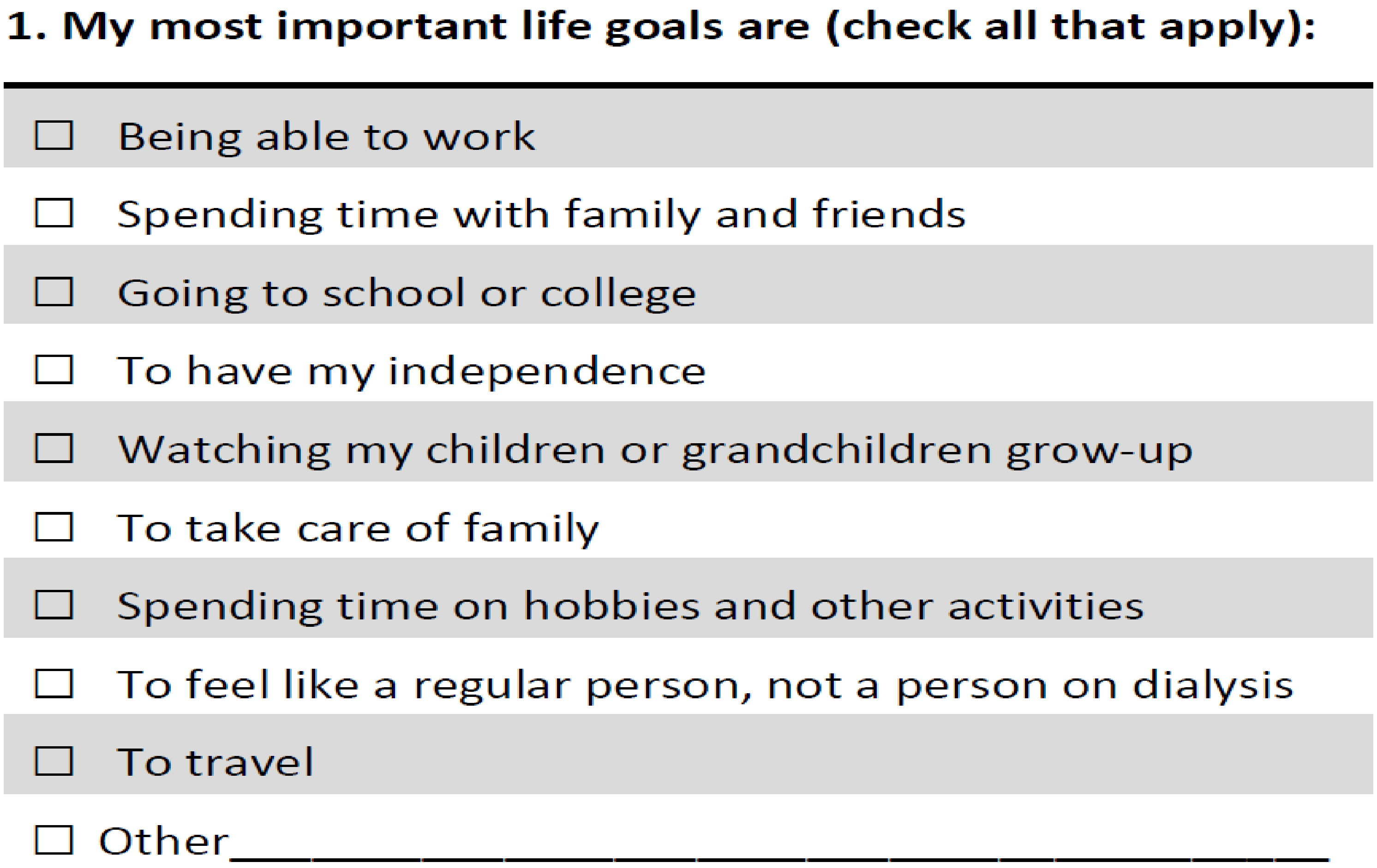
Discussion: Appropriateness of Practitioner Waitlist Measure

- Based on proposed measure specifications and discussions, how do you feel about a practitioner waitlisting measure?
- Would such a measure potentially improve access to kidney transplantation?
- Do you have concerns about negative consequences of implementation of such a measure?
- Do you think the benefits to patients outweigh the risks?

Assessing Transplant Education: Feedback Requested

- Example: Life Goals Survey
- Recently developed and validated patient reported outcome (electronic and paper versions)
- Low burden for completion
- Assesses patient voice with respect to whether their goals are being met
- Comparable assessment for transplant education?

Assessing Transplant Education: Feedback Requested



1. My most important life goals are (check all that apply):

- ☐ Being able to work
- ☐ Spending time with family and friends
- ☐ Going to school or college
- ☐ To have my independence
- ☐ Watching my children or grandchildren grow-up
- ☐ To take care of family
- ☐ Spending time on hobbies and other activities
- ☐ To feel like a regular person, not a person on dialysis
- ☐ To travel
- ☐ Other___________________________________

Assessing Transplant Education: Feedback Requested

	Strongly Disagree	Disagree	Neither Disagree/Agree	Agree	Strongly Agree
a. At least one member of my care team knows about my life goals.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I believe it is important at least one member of my care team talks with me about my life goals.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. My treatment plan is consistent with my life goals.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Wrap-up – Waitlist Measures

- Structure/Focus – 4 Measures
  - Standardized Waitlist Ratio (SWR) First Year (can be all patients, not just Medicare
  - Standardized Waitlist Ratio First Year and Beyond (accounts for patient transfers and includes adjustment for dialysis vintage)
  - PPPW
  - Active PPPW

Wrap-up – Waitlist Measures

- Exclusions: Age 75 years or older, nursing home residence, hospice
- Medical Risk (Comorbidity) Adjustment – from 2728, and Medicare claims
- Social Risk Adjustment – insurance status, ADI
- Transplant center adjustment

Wrap-up – Referral Measures

- Structure/Focus –
  - Standardized Referral Ratio (SWR) First Year (can be all patients, not just Medicare
  - Standardized Referral Ratio First Year and Beyond (accounts for patient transfers and includes adjustment for dialysis vintage

Wrap-up – Referral Measure

- Exclusions: Age 75 years or older, nursing home residence, hospice
- Medical Risk (Comorbidity) Adjustment – from 2728, and Medicare claims
- Social Risk Adjustment – insurance status, ADI
- Transplant center adjustment

Thank You

Public Comment