

**Evaluation of Racial Disparities in Access to Kidney Transplantation
in the New National
Kidney Allocation Policy (Aim 2)**

IRB#00081580

**Evaluation of Racial Disparities in Access to Kidney Transplantation
in the New National
Kidney Allocation Policy (Aim 2)**

Protocol Dated Aug 25th 2017

NCT02879812

Title: Evaluation of Racial Disparities in Access to Kidney Transplantation in the New National Kidney Allocation Policy (Aim 2)

Investigators: Rachel E Patzer, Cam Escoffery, David Howard, Stephen Pastan, Laura Plantinga, Nicole Turgeon, Rebecca Zhang, Janice Lea, Sumit Mohan

C.4. Specific Aim 2. To evaluate the impact of a systems-level approach to providing tailored transplant performance feedback and education about the kidney allocation policy, we will conduct a multicomponent, clinical effectiveness-implementation study among 750 US dialysis facilities with racial disparities in waitlisting. Based on our preliminary data and access to national data on dialysis facility performance in waitlisting and transplant, we anticipate that *increasing provider knowledge about the allocation policy within facilities that have racial disparities in waitlisting will reduce national disparities in access to the waiting list.*

INTRODUCTION AND BACKGROUND

The public health burden of kidney failure in the United States is substantial, with more than 600,000 end-stage renal disease (ESRD) patients. There are two main treatments for kidney disease – dialysis or kidney transplantation. A complex, multi-tiered national system regulates kidney disease care, reimbursement, and transplantation, creating barriers to overcoming the significant racial disparities that exist in transplantation, the most effective treatment for ESRD. The federal Organ Procurement and Transplantation Network of the United Network for Organ Sharing oversees the allocation of all deceased donor organs in the US, and on Dec. 4, 2014, a major change to the allocation policy was implemented that is expected to impact racial disparities in transplantation access. We propose to study the impact of the natural experiment offered by enactment of this new kidney allocation policy on reducing disparities in the key steps of referral for transplant evaluation, waitlisting, and transplantation, each of which have complexities for measurement at the local and national level. Based on national data that we have used to develop a systems-level practice, we will disseminate a systems-level practice of providing feedback to dialysis centers about their transplant performance to improve overall waitlisting rates and decrease disparities in kidney transplantation.

Within the Southeastern US, where access to kidney transplantation is the lowest and racial and socioeconomic disparities in transplant access are the most substantial, we will work with our Dissemination Advisory Board, which includes relevant stakeholders within the kidney health care system, to finalize intervention materials (Objective 1) and then disseminate dialysis facility-specific performance feedback reports as part of a multicomponent intervention (educational videos for staff and patients; webinar for staff) using a clinical effectiveness-implementation study⁵⁰ design among a national sample of 1500 dialysis facilities with racial disparities in waitlisting access (Objective 2). Key outcomes will include 1-year disparity reduction in dialysis facility-level waitlisting (primary outcome), and change in knowledge, intent to refer for transplant, communication to patients, and staff training about the allocation policy (secondary outcomes).

The purpose of Aim 2 is to test a systems-level approach to disseminate a multicomponent intervention consisting of tailored, facility-specific performance report that will reflect a facilities performance (with respect to transplant and racial disparities in waitlisting) in the era of the new national kidney allocation policy and educational materials targeting dialysis facility Medical Directors, staff, and patients. We will implement a multicomponent intervention to ~1500 dialysis facilities in all 18 ESRD Network regions across the US to extend the influence of the national allocation policy in reducing disparities in early steps in kidney transplant access. In Objective 2, we will conduct a pragmatic, clinical effectiveness-implementation study⁵⁰, which will not only test the effectiveness of this approach, but even if the approach is not effective in reducing disparities, providing important information through implementation will still occur. The rationale for this design is based on several evidence-based criteria.⁴⁵ In this study, there is strong face validity for both clinical and implementation activities, based on experts from our Coalition. There is a strong base of indirect evidence, defined as clinical effectiveness data from a different but associated population, through a Cochrane Review of performance feedback reports⁵¹ and

through our prior work that used a performance feedback report as a major component of an intervention among GA dialysis facilities in the RaDIANT study, where we found that disparities in referral were reduced 36% over 9 months among the intervention vs. control facilities.³¹ Feedback reports to dialysis facilities are minimal risk quality improvement activities that are routinely delivered to facilities in ESRD Networks, where similar reports have been used as a main component of the intervention in the national Fistula First Breakthrough Initiative,⁵⁰ for increasing influenza and pneumococcal vaccination among ESRD patients within facilities,⁴² and for reducing racial disparities in kidney transplant referral.³⁰ Finally, there is a strong implementation momentum of material related to the kidney allocation system, since it started in December 2014, and there are many potential ESRD patients who could benefit from this policy; a total of 74,443 current ESRD patients (of which nearly half are AA) have been on dialysis for more than 5 years and would likely have short wait times if referred for transplant evaluation now.²⁶ Because evidence also suggests that performance feedback reports are more effective when combined with a multicomponent intervention strategy,⁵² including both verbal and written communications, we will combine the report with educational videos (~5 minutes) for staff and patients and an educational webinar for dialysis facility staff. While our intervention efforts will primarily target Medical Directors, the leaders of the dialysis facility, educational material and outcomes will assess whether the Medical Directors disseminated information about the new kidney allocation policy and transplant information to dialysis facility staff and ESRD patients.

Objective 1 – *To develop a dissemination and feedback report as part of a multicomponent intervention for US dialysis facilities.*

STUDY DESIGN AND METHODS

Dissemination Advisory Board - Partnering stakeholders will play a key role in the dissemination of this research. In Year 1 (Q1), a Dissemination Advisory Board will be convened among the study Co-Is, regional members of the Southeastern Kidney Transplant Coalition, and other national partners, including the National Kidney Foundation, the American Association of Kidney Patients, dialysis facility social workers and staff, ESRD patients, researchers, and key policy partners including ESRD Network 6 leadership and staff, members from the National ESRD Network Board (Dr. Pastan), and a representative from the UNOS kidney committee (Turgeon). Several Medical Directors, nephrologists, and social workers from dialysis facilities will also be included (see Letters of Support). Under the direction of Stephen Pastan (Co-I; Chair of Southeastern Kidney Transplant Coalition) and the PI (Patzner), stakeholder feedback about the incentives or barriers that exist will ensure that dialysis facilities understand the new kidney allocation policy and communicate information to facility staff and ESRD patients to encourage improved access to kidney transplantation. The volunteer Dissemination Advisory Board will meet on a virtual basis monthly for 4 months to develop communication pieces for use in formative testing (e.g., feedback reports, webinar) and to draft surveys to measure secondary study outcomes; they will finalize intervention materials following formative evaluation (described below).

Multicomponent Intervention. Similar to our prior dialysis facility-level interventions^{30,42,44}, the multicomponent intervention will consist of the feedback report as well as a ~45-minute educational webinar for dialysis facility Medical Directors and staff and a separate ~5-minute educational video for patients and staff.

Performance Feedback Reports. Performance feedback reports are defined as “a summary of clinical performance of health care over a specified period of time aimed at providing information to health professionals to allow them to assess and adjust their performance.”⁵¹ As in our prior work,³⁰ a performance feedback report will be developed by the Dissemination Advisory Board using evidence-based approaches^{31,42} and then provided to facility Medical Directors for pretesting. We expect the report to emphasize the most relevant information about the new kidney allocation policy for dialysis facilities, including tailored, facility-specific information (from publicly available, national Dialysis Facility Report data that we have previously used in research analyses²⁹ and for facility-specific reports³⁰) on the mean time on dialysis for patients in that facility, since transplant eligible-patients with longer dialysis may be more likely receive a transplant faster, compared to those with shorter dialysis time. In addition, the report will emphasize transplant access performance measures, such as waitlisting and transplantation,

including the magnitude of racial disparity, detailing when a facility is performing below the national or regional average. Evidence-based strategies will be used for the communication piece.⁴⁵ For example, one figure may emphasize simple communication about the kidney allocation policy, whereas another report may emphasize benchmarking to compare how the facility compares to other facilities in that state or ESRD Network region. One figure may emphasize information about racial disparity in transplant access and show the proportion of AA patients within the facility with corresponding transplant access measures. Based on 108 comparisons from 70 studies in a Cochrane Review, feedback performance reports are most effective when they include an action plan.⁵¹ This report will offer consistent messaging regarding action plans (e.g., educating patients about transplant). Individualized reports will be emailed to facility staff as described below, but will also be made available for download on the same website as the educational videos and webinars.

Educational Video for Staff & Patients –The Dissemination Advisory Board will develop a short educational video targeted to dialysis facility staff (nephrologists, nurses, & social workers) that describes the new kidney allocation policy and how it impacts dialysis facilities, as well as a video targeted to patients within facilities to explain in plain language (6th-8th grade level) the transplant process and allocation policy. These videos will be hosted on a website and usage tracked. We (Patzner, Turgeon, Pastan, Escoffery) have prior experience making videos for patients and staff

Educational Webinar for Medical Directors and Facility Staff – Dr. Turgeon (a UNOS representative) has agreed to participate in the Advisory Board and on the educational webinar about the kidney allocation policy. Content will be approved by the Dissemination Advisory Board and targeted to Medical Directors and facility staff. We (Patzner, Pastan, Krisher) have experience developing content and hosting webinars for dialysis facility staff (n=12 webinars in 2014 alone) with 81% attendance (<http://www.esrdnetwork6.org/improving-care/transplant.html>). The webinar materials will also be hosted on a website for study participants to access.

Formative Evaluation of Intervention Materials – Formative evaluation is a rigorous assessment process designed to identify potential influences on the progress and effectiveness of implementation efforts to optimize the potential for success of the intervention.⁵⁰ The purpose of formative testing in our study is to conduct a rigorous assessment approach to refine, improve, tailor and adapt the intervention to our relevant target population (Medical Directors) prior to the effectiveness-implementation study. In Year 2, Q1-Q2, we will conduct in-person, formative testing of the dissemination materials in n=6 of the >600 dialysis facilities in ESRD Network 6 to ensure that the materials developed incorporate the most persuasive content and most effective way to communicate information to the target population of dialysis facility Medical Directors (nephrologists). Following informed consent, Medical Directors will be surveyed about their kidney allocation policy knowledge and whether they have made any efforts to communicate information about the changes to the kidney allocation policy to nephrologists, staff, and ESRD patients in their facilities. Next, we will give the draft performance feedback report to Medical Directors and ask them to view the educational videos within 1 week, and then follow up with structured interviews among Medical Directors and staff to assess whether there were any missing educational domains from the feedback report to try to identify any gaps in understanding about the kidney allocation policy and how the policy influences their facility or ESRD patient population. For example, we will ask whether there are any remaining questions about the kidney allocation policy, what incentives they need to educate their staff, and their opinions about what other information might help to influence transplant access among different patient populations (e.g., AA patients, females, patients with low SES, etc.). Draft questions for this formative evaluation and draft surveys that that will be pretested and then used in the effectiveness-implementation study are included in the Social Research section of IRB. We will assess how long facility Medical Directors estimate it would take to educate staff about the kidney allocation policy to ensure 3 months is adequate time to measure outcomes. Medical Directors will be offered gift card incentives for participation in the structured interviews and surveys.

Objective 2 - *To evaluate the clinical effectiveness and feasibility of implementing a feedback report to dialysis facilities with racial disparities in waitlisting access.*

We will test the effectiveness and implementation of the performance feedback report among ~1500 dialysis facilities in 18 ESRD Networks across the US to examine whether this dissemination intervention improves facility waitlisting performance. Facilities will be randomized to the intervention or usual care. The intervention group will receive a performance feedback report, educational videos, and the webinar, while the usual care comparison group will receive an educational pamphlet from UNOS. We expect to survey Medical Directors at baseline and at 3 months (exact time will depend on formative testing) to assess changes in secondary outcomes.

PARTICIPANT SELECTION

Recruitment of Dialysis Facilities – Executive Directors of all 18 ESRD Networks were contacted and invited to participate in this study, and all 18 US ESRD Networks, representing 50 states (and 3 territories) have committed support in participation. All ESRD Networks have a requirement to focus on disparity reduction in the quality improvement projects among dialysis facilities, and transplant referral is also a priority area in the 2015 CMS ESRD Network Statement of Work and is expected to be of continued importance.³² To encourage participation of ESRD Networks across the nation, we will develop annual transplant performance reports with tailored feedback detailing Network's performance in waitlisting and transplantation with respect to other Networks, as well as some of the key features that will be included in the facility-specific reports to encourage participation.

Eligibility Criteria and Description of Potential Study Population – Facilities with at least n=11 patients (at least 4 AA patients) in their facility with a waitlisting disparity will be eligible for participation, since measured outcomes focus on disparity reduction and facilities with small proportions of AA or a small number of patients may be difficult to classify as a disparity facility. Of the facilities in the 18 ESRD Networks, n=1529 dialysis facilities had a racial disparity in waitlisting in 2014. Demographics of participating facilities with a racial disparity in waitlisting are: AA (42.3%) and 53.0% white; mean age 61.7 years; 65.5% unemployed, 11.4% Medicaid insurance; and 25.8% of patients waitlisted, and mean number of staff / facility 17.7. We expect ~1% of facilities will close in 1 year or there may be an improvement in racial disparities (from 2011) once we start the study, thus we expect a minimum of N=750 facilities will participate.

STUDY DESIGN AND METHODS

Study Procedures – Because there may be significant heterogeneity in dialysis facilities and patient and staff populations across the 18 participating ESRD Networks, we will randomize dialysis facilities that were not included in formative testing within each ESRD Network region to either the multicomponent intervention (feedback report, webinar, and videos) or comparison group (usual care plus UNOS educational brochure). At baseline (Year 2, Q3-Q4), all eligible dialysis facility Medical Directors in both the intervention and control group will receive an email from their ESRD Network Executive Director a web-based survey (HIPAA-compliant surveymonkey) with informed consent. For those who consent to participate (in reporting secondary outcome measures), baseline surveys will then be administered. Within one week of this email (or immediately after for those that complete a baseline survey), all facility Medical Directors from participating facilities will be emailed a UNOS pamphlet and instructed to share with staff; intervention facilities will be emailed facility-specific performance feedback report and videos, and information about the educational webinar. At 3 months, all facility Medical Directors who consented to participate will be emailed follow-up surveys by their respective ESRD Network Executive Director to assess secondary outcomes. Our prior work has shown >90% response rates by Medical Directors when surveys are mailed directly from the ESRD Network.⁵³ Medical Directors will be offered an electronic gift card incentive (\$10) for participation.

Effectiveness Measure Outcomes – To test the effectiveness of this intervention, several outcomes will be assessed via surveys and surveillance data. Waitlisting data from 1 year post-intervention will be assessed using nationally available Dialysis Facility Report surveillance data in order to assess disparity reduction at the facility level. Follow-up surveys will be emailed to all Medical Directors at 3 months to test change in knowledge about the kidney allocation policy and whether Medical Directors have implemented

any staff training regarding the allocation policy within their dialysis facility, what methods the facility has used to educate ESRD patients about the kidney allocation policy, and whether the policy influenced facility Medical Directors' intent to refer more patients for transplantation.

Measures are described below. Surveys will be pilot tested in formative phases and finalized with approval by the Dissemination Advisory Board.

1) Change in Waitlisting Disparity (Primary Outcome) – We will calculate facility racial disparity in waitlisting one year prior and post-intervention as the difference between the proportion of AA vs. whites waitlisted.

2) Change in Knowledge about the Kidney Allocation System (Secondary Outcome) – We will survey Medical Directors using a 20-question scale measuring knowledge about the kidney allocation system, and general transplant knowledge, based on a validated scale we have used among dialysis staff and patients.⁵⁴

3) Change in Staff Training about Kidney Transplant and the Allocation System (Secondary Outcome) – We will assess at baseline whether Medical Directors have trained their staff about transplantation and/or the details of the kidney allocation policy. We will ask whether the Medical Director provided training about transplant or the kidney allocation policy in the prior 3 months after intervention delivery, and information about training (e.g., did they hold a training session, send an email, watch video presentations, etc.). Details about trainings will be collected to inform best practices for staff training for future scale-up.

4) Evidence of Communication to Patients (Secondary Outcome) – To ensure that dialysis facility Medical Directors communicate information about the kidney allocation system to their staff and patients, we will track the educational video website usage by asking users to input user type, facility name, and location. This will allow us to track intervention dose and usage statistics such as number of uses by facility, time in application, etc. We have previously tracked other mobile educational initiatives through Google Analytics with success.⁵⁵

5) Change in Intent to Refer Patients to Kidney Transplantation (Secondary Outcome) – We will assess the current referral practices of facilities by surveying Medical Director about the estimated proportion of patients interested, eligible, and referred for transplant in their facility at baseline and at 3 months post- intervention. We will ask questions about the estimated % of patients referred for transplant by specific patient characteristics (e.g. age, race/ethnicity, SES, time on dialysis, etc). A similar survey has been used in our Network in the past⁵³ and will be finalized by the Dissemination Advisory Board in objective 1. Obtaining actual referral data is only possible for ESRD Network 6 dialysis facilities. However, our prior analyses examining dialysis staff-reported referrals and actual referrals to transplant centers show high correlation ($r=0.79$; $p<0.01$).

Implementation effect measures: We will use an adaptation of the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework³⁸ for evaluating the public health impact of this health policy change.⁴⁵ This framework builds upon the conceptual models of Rogers⁵⁶ and Green and Krueger⁵⁷ in this hybrid effectiveness-implementation study. A description of each of these measures and how they are applied to evaluating the successful implementation of a policy intervention are described in the table above. Effectiveness and Adoption measures are described in detail above. Implementation will be assessed by calculating a composite measure, or 'crude implementation index' for each facility as the sum of each secondary outcome (dichotomized at the median). We will conduct qualitative analyses of select dialysis facility providers that were successful intervention implementers ($n=5$) and non-

Table 2. Re-AIM Components and Study Measures to Track Implementation

RE-AIM Components	Definition	Study Measures
Reach	Number or % affected by policy; population characteristics	1. % of participating facilities with racial disparities / all facilities with racial disparities 2. Comparison of participating vs. non-participating facilities
Effectiveness	Change in outcomes	Primary outcome: Racial disparity in waitlisting
Adoption	Proportion that adopt policy or intervention	Secondary Outcomes: 1. Knowledge about allocation system 2. Staff training about transplant & allocation 3. Communication to patients 4. Intent to refer for kidney transplantation
Implementation	Extent to which an intervention is delivered as intended	1. Crude implementation index 2. Qualitative analysis of implementers vs. non-implementers
Maintenance	Long-term behavior change	Longer-term (1-year) adoption measures among a subset of facilities

implementers (n=5). At 1 year via phone interviews. These providers will be selected among the providers who completed the follow-up survey and already provided consent for the intervention. Phone interviews will be recorded and transcribed to help us better understand how to improve the intervention for the future. Providers who participate in the interview will be given \$30 gift cards as an incentive.

Other Measures. To explore potential moderators of the effectiveness of this system-level intervention, we will examine facility characteristics (region, facility size, profit status, etc), characteristics of patients in facilities (e.g., race, SES, comorbidities, etc), and neighborhood characteristics. We will include process measures for the intervention (receipt of intervention and self-report) to evaluate utility, value, satisfaction and reactions to intervention materials to ensure optimal future dissemination of interventions to other US dialysis facilities.

STATISTICAL ANALYSES

We will evaluate our main outcome of change in AA vs. white racial disparity reduction in waitlisting in the year post-intervention compared to the year prior to the intervention among the intervention vs. control facilities (intent to treat) using generalized linear models⁴⁸ to account for potential correlation of facilities within Networks. Secondary analyses will examine facility- and patient-level modifiers of the intervention. Change in each of the secondary outcomes will be examined. *We hypothesize that increasing provider knowledge about the allocation policy in facilities with racial disparities will reduce waitlisting disparities.* Follow-up interviews will be transcribed verbatim and a codebook will be developed for qualitative analysis. Thematic analysis of key facilitators and barriers will be conducted to inform practice change.⁵¹

Sample Size and Power. With 18 ESRD Networks participating (representing 1500 dialysis facilities with a waitlisting disparity), we estimate a minimum of ~375 facilities (average of 70 patients/facility) in each control/intervention group (total N=750), after accounting for ~1% loss from facilities that may close in the 1-year evaluation and yearly fluctuation in waitlisting disparity. This will achieve 80% power (at $\alpha=0.05$) to detect a difference of 10% in the waitlisting disparity ratio (%AA waitlisted/%white waitlisted) in the intervention vs. control group at 1 year, assuming the same disparity ratio (0.6) by group at baseline and an intraclass correlation coefficient of 0.06 among patients in a facility (based on RaDIANT). We found a 36% disparity reduction in the RaDIANT study after 9 months³¹; thus we expect that a 10% effect within 1-year is achievable.

DATA AND SAFETY MONITORING PLAN (DSMP) - A Dissemination Advisory Board (comprised of members of the SEKTC, and regional and national partners in the kidney transplant community) will be responsible for finalizing interventional material including performance feedback reports, webinars, and educational videos; See DSMB section in eIRB 81580.