

UCSF

UC San Francisco Previously Published Works

Title

The ASCENT (Allocation System Changes for Equity in Kidney Transplantation) Study: a Randomized Effectiveness-Implementation Study to Improve Kidney Transplant Waitlisting and Reduce Racial Disparity.

Permalink

<https://escholarship.org/uc/item/6ph488r5>

Journal

Kidney International Reports, 2(3)

ISSN

2468-0249

Authors

Patzer, Rachel

Smith, Kayla

Basu, Mohua

et al.

Publication Date

2017-05-01

DOI

10.1016/j.ekir.2017.02.002

Peer reviewed

The ASCENT (Allocation System Changes for Equity in Kidney Transplantation) Study: A Randomized Effectiveness-Implementation Study to Improve Kidney Transplant Waitlisting and Reduce Racial Disparity



Rachel E. Patzer^{1,3,4}, Kayla Smith¹, Mohua Basu¹, Jennifer Gander¹, Sumit Mohan², Cam Escoffery³, Laura Plantinga⁵, Taylor Melanson⁶, Sean Kalloo², Gary Green⁷, Alex Berlin⁸, Gary Renville⁹, Teri Browne¹⁰, Nicole Turgeon¹, Susan Caponi¹¹, Rebecca Zhang¹² and Stephen Pastan⁵

¹Department of Surgery, Division of Transplantation, Emory University School of Medicine Atlanta, Georgia, USA; ²Department of Medicine, Division of Nephrology, College of Physicians & Surgeons, and Department of Epidemiology, Mailman School of Public Health, Columbia University, New York, New York, USA; ³Department of Epidemiology, Rollins School of Public Health, Emory University School of Medicine, Atlanta, Georgia, USA; ⁴Department of Behavioral Sciences and Health Education, Rollins School of Public Health, Emory University School of Medicine, Atlanta, Georgia, USA; ⁵Department of Medicine, Division of Renal Medicine, Emory University School of Medicine, Atlanta, Georgia, USA; ⁶Department of Health Policy Management, Rollins School of Public Health, Emory School of Medicine, Atlanta, Georgia, USA; ⁷American Association of Kidney Patients, Tampa, Florida, USA; ⁸Southeastern Kidney Transplant Coalition, Atlanta, Georgia, USA; ⁹National Kidney Foundation, Atlanta, Georgia, USA; ¹⁰University of South Carolina, College of Social Work, Columbia, South Carolina, USA; ¹¹US ESRD Network 2, Lake Success, New York, USA; and ¹²Department of Biostatistics, Rollins School of Public Health, Emory University School of Medicine, Atlanta, Georgia, USA

Introduction: The United Network for Organ Sharing (UNOS) implemented a new Kidney Allocation System (KAS) in December 2014 that is expected to substantially reduce racial disparities in kidney transplantation among waitlisted patients. However, not all dialysis facility clinical providers and end-stage renal disease (ESRD) patients are aware of how the policy change could improve access to transplantation.

Methods: We describe the ASCENT (Allocation System Changes for Equity in Kidney Transplantation) study, a randomized, controlled effectiveness-implementation study designed to test the effectiveness of a multicomponent intervention to improve access to the early steps of kidney transplantation among dialysis facilities across the United States. The multicomponent intervention consists of an educational webinar for dialysis medical directors, an educational video for patients and an educational video for dialysis staff, and a dialysis facility-specific transplantation performance feedback report. Materials will be developed by a multidisciplinary dissemination advisory board and will undergo formative testing in dialysis facilities across the United States.

Results: This study is estimated to enroll ~600 US dialysis facilities with low waitlisting in all 18 ESRD networks. The co-primary outcomes include change in waitlisting and waitlist disparity at 1 year; secondary outcomes include changes in facility medical director knowledge about KAS, staff training regarding KAS, patient education regarding transplantation, and the intent of the medical director to refer patients for transplantation evaluation.

Discussion: The results from the ASCENT study will demonstrate the feasibility and effectiveness of a multicomponent intervention designed to increase access to the deceased donor kidney waitlist and to reduce racial disparities in waitlisting.

Kidney Int Rep (2017) 2, 433–441; <http://dx.doi.org/10.1016/j.ekir.2017.02.002>

KEYWORDS: education; ESRD Networks; Kidney Allocation System; kidney transplantation; multicomponent intervention; waitlisting

© 2017 International Society of Nephrology. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Correspondence: Rachel E. Patzer, Assistant Professor, Emory University School of Medicine, Division of Transplantation, 101 Woodruff Circle, Atlanta, GA 30322. E-mail: rpatzer@emory.edu

Received 30 August 2016; revised 28 December 2016; accepted 2 February 2017; published online 10 February 2017

Current literature documents substantial disparities in access to kidney transplantation waitlisting, including variation in waitlisting across the United States.^{1–6} To address some of the disparities in transplantation access, the United Network for Organ

Sharing (UNOS) implemented a new kidney allocation system (KAS) in December 2014 that changed how kidneys are allocated to potential recipients across the United States.⁷ Under the previous KAS, the most important determinant of receiving a new organ was time spent on the waiting list, with the clock starting when the transplantation center placed the patient on the waitlist, rather than when the patient started dialysis treatment. Under the new allocation system, the waiting time reverts back to the time of dialysis treatment initiation for all dialysis patients. Because African Americans on average spend a longer time on dialysis before referral for transplantation evaluation compared with white patients,⁸ this is 1 major aspect of the policy that is expected to reduce racial disparities in access to multiple transplantation steps. However, nephrologists and other dialysis staff may not be aware that patients with a longer time on dialysis who are not yet on the waitlist may receive a kidney transplantation more quickly under the new KAS.⁹ Because most patients with end-stage renal disease (ESRD) in the United States are initially treated at a dialysis facility,⁹ these facilities play a key role in educating patients and referring them to a transplantation center to undergo a transplantation evaluation.

Previous research suggested that multicomponent dialysis facility–based interventions conducted with the support of government agencies, such as Centers for Medicare & Medicaid and/or ESRD Networks, might be effective in improving dialysis access,¹⁰ which would increase vascular access¹¹ and increase referral for transplantation. Audit and feedback reports, otherwise known as performance feedback reports,¹² were used in poorly performing dialysis facilities. Furthermore, research showed that when clinical interventions had a substantial evidence base, and there was need for expediency in ensuring the intervention was rapidly translated from research into practice, an effectiveness-implementation hybrid study design might be particularly useful to increase the usefulness and policy relevance of clinical research.¹³ Such a hybrid model allows for evaluating the effectiveness of a multicomponent intervention in a real-life setting while also assessing the implementation and potential sustainability of the intervention.

In our planned ASCENT (Allocation System for Changes in Equity in Kidney Transplantation) study, we will test the effectiveness of educating dialysis physicians, staff, and patients on this recent KAS policy change on waitlisting using this effectiveness-implementation study framework to more quickly implement the intervention into practice if it is deemed

effective. We will create a multicomponent intervention consisting of a webinar for dialysis facility medical directors, an educational video for patients, an educational video for dialysis facility staff, and a dialysis facility–specific transplantation performance feedback report for medical directors detailing the transplantation performance of the facility and communicating key relevant aspects of the new KAS in context with the data of the facility. An estimated 600 dialysis facilities across the United States with low kidney transplantation waitlisting in all 18 ESRD networks will be randomized to receive either the multicomponent intervention (intervention) or a UNOS brochure describing the recent KAS change (control). We will use a randomized effectiveness-implementation study design to test the effectiveness of the multicomponent intervention among dialysis facilities with low waitlisting, with a goal of increasing access to the deceased donor kidney waitlist and reducing racial disparities in waitlisting.

STUDY DESIGN AND METHODS

Study Overview

A dissemination advisory board (DAB), including relevant stakeholders within the kidney health care system, will be convened to develop, finalize, and disseminate intervention materials among an estimated national sample of ~600 dialysis facilities with low waitlisting. Co-primary outcomes will include (i) change in proportion of patients waitlisted, and (ii) disparity reduction in proportion of patients waitlisted in a dialysis facility after 1 year. Secondary outcomes include changes from baseline to 3 months in medical director knowledge about transplantation and KAS, as well as the intent of the medical director to refer patients for transplantation.

Eligibility Criteria and Description of Potential Study Population

All 18 ESRD networks will be contacted and invited to participate in this study. To encourage participation of ESRD networks across the nation, we will develop annual transplantation performance reports with tailored feedback detailing the performance of each participating network in waitlisting and transplantation compared with other ESRD networks across the United States, as well as some of the key features that will be included in the dialysis facility–specific reports. These network-level feedback reports will be shared only with ESRD network staff, rather than the dialysis facilities within their respective network.

Facilities with low waitlisting, which have at least 11 patients overall and at least 4 African American

patients, will be eligible for participation, because measured outcomes focus on disparity reduction and facilities with small proportions of African Americans; a small number of patients may be difficult to classify as a facility with a disparity. Low waitlisting will be defined as the lowest national tertile for 2014 (most recent data available) at randomization. Of the 1529 dialysis facilities meeting eligibility criteria across the United States, we estimate ~40% of those invited (600 facilities) will agree to participate (Figure 1).

Study Procedures

Dissemination Advisory Board

The DAB of partnering stakeholders will be created among study co-investigators and national partners, including the National Kidney Foundation and the American Association of Kidney Patients, dialysis facility medical directors, nephrologists, social workers, ESRD patients, researchers, key policy partners, including ESRD Network 6 leadership and staff, UNOS, and regional members of the Southeastern Kidney Transplant Coalition (an academic–community collaboration among partners in North Carolina, South Carolina, and Georgia committed to eliminating health disparities in kidney transplantation). Stakeholder feedback regarding patient barriers to kidney transplantation and development of educational materials will ensure that these intervention materials are

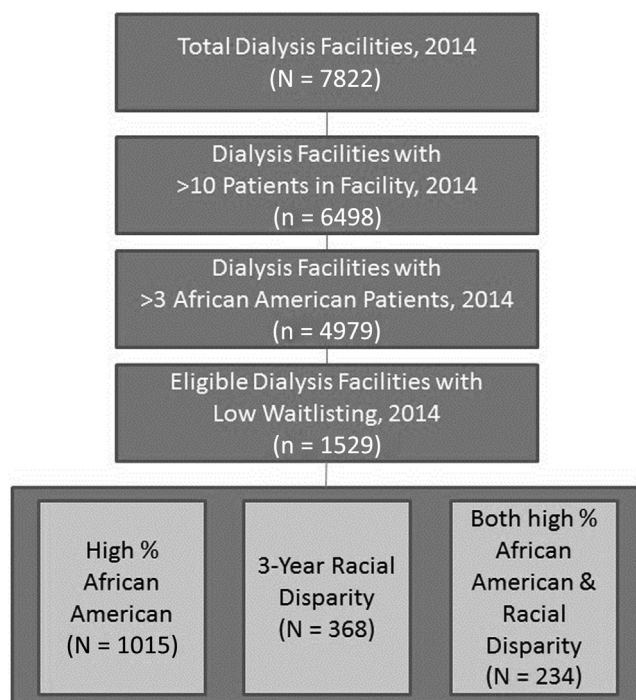


Figure 1. Selection criteria for dialysis facilities eligible to participate among 18 end-stage renal disease networks invited to ASCENT Study.

appropriate for dialysis facilities to understand the recently changed KAS and to help communicate information to facility staff and ESRD patients to encourage improved access to kidney transplantation. The volunteer DAB will meet via conference phone calls monthly for ~6 months to develop the multi-component intervention and finalize surveys. After materials are created, the DAB will review materials and provide feedback for improvement. Detailed information about the intervention material and the role of the DAB in developing these is described below.

INTERVENTION MATERIALS

Transplantation Performance Feedback Reports

The transplantation performance feedback report will reflect the performance of a dialysis facility with respect to kidney transplantation waitlisting and racial disparities in waitlisting, and will be provided to facility medical directors. The report will note information about the recent changes in KAS that are most relevant for the dialysis facility and will display facility-specific transplantation access performance measures, such as facility-specific waitlisting and racial disparity in waitlisting data, comparing the performance of the facility to the national average. An example potential feedback report is provided in Figure 2. The DAB will review several versions of the feedback report and discuss which layouts, content, and messages are best tailored to dialysis facilities with low waitlisting. Individualized reports will be emailed to intervention-assigned dialysis facility staff by their respective ESRD networks.

Educational Video for ESRD Patients

An ~10-minute educational video will be produced for dialysis patients, highlighting the benefits of kidney transplantation, disputing common misconceptions about transplantation, and motivating patients through real patient stories on overcoming barriers to transplantation. The video is intended to educate and encourage patients to talk to their providers about being referred for kidney transplantation. The DAB will help recruit patients for this video and provide input on the video script, length, content, and format, as well as feedback on future revisions of the video.

Educational Video for Dialysis Facility Staff

An ~10-minute educational video targeted to dialysis facility staff (nephrologists, nurses, and social workers) will be created that describes racial disparities in transplantation, recent changes in the KAS and its effort to reduce disparities, and the important role of dialysis staff in educating patients about kidney

Transplant Performance Feedback Report

110000

ABC Dialysis, Inc.



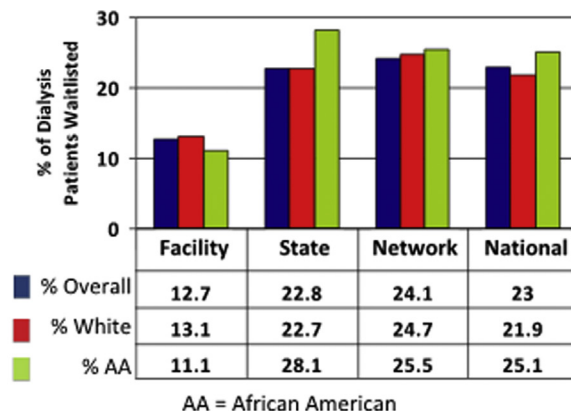
- The Kidney Allocation System changed in December 2014, giving priority to patients with longer time on dialysis in efforts to improve equity and reduce racial disparities in kidney transplantation.
- Your dialysis facility had among the lowest percentage of patients on the kidney transplant waitlist (Fig. 1).
- In 2014, your facility had a lower percent of African American patients compared to white patients on the kidney transplant waitlist (Fig. 2).
- Your facility has a high number of patients, including African Americans, who have been on dialysis for ≥ 4 years (Fig. 3). Patients will now receive credit on the deceased donor kidney waitlist for time spent on dialysis. As a result, their wait time to receive a deceased donor kidney may be reduced.

How Is Your Facility Performing When Compared To Other Dialysis Facilities?

Figure 1. Distribution of the Percent of Dialysis Patients Waitlisted for Kidney Transplantation at U.S. Dialysis Facilities, 2014

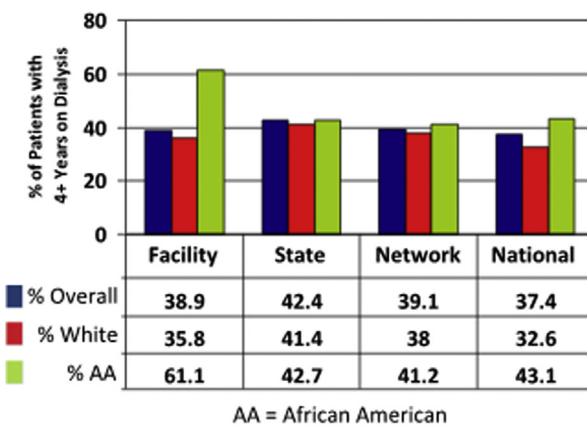


Figure 2. Percent of Dialysis Patients on the Waitlist by Race Across Geographic Areas, 2014



Next Steps

Figure 3. Percent of Patients with ≥4 Years on Dialysis Across Geographic Areas by Race, 2014



- Continue educating all patients about the benefits of kidney transplant at least annually.
- Regularly review your dialysis population to determine their interest in kidney transplantation.
- Identify and refer patients who have been on dialysis for several years, as their years on dialysis will now count toward their transplant waiting time.
- Refer all appropriate patients for transplantation as early as possible.
- Follow all patients from transplant evaluation to waitlisting, and remember to notify the transplant center with any changes in patients' status that may affect their transplant candidacy.



For more information about transplant, contact the ASCENT (Allocation System Changes for Equity in kidney Transplantation) Study staff at info@ascenntotransplant.org
 Data source for figures was United States Renal Data System (USRDS), 2014.

Figure 2. Example of ASCENT feedback report for dialysis facility medical directors.

transplantation and being involved with patients throughout the entire transplantation process. The video will feature clinical staff, such as a social worker, nurse, and nephrologist, as well as patient testimonials to emphasize the great impact that

proactive dialysis staff have on their patients' transplantation journeys. The DAB will help create the video script content, select graphics, provide feedback on video length, and review the video to provide feedback for future edits.

Educational Webinar for Medical Directors and Facility Staff

The DAB will work with a UNOS physician representative to create and present an ~30-minute webinar targeted to dialysis facility medical directors, physicians, and other staff involved in transplantation education at the dialysis units. The webinar will discuss benefits of kidney transplantation, recent changes in KAS, implications of KAS on reducing racial disparities in waitlisting, and how dialysis facility staff can assist patients throughout the transplantation process. The webinar will be presented live with a question-and-answer session, and will also be recorded for those who cannot attend the live session. It will be hosted on the study website for ASCENT intervention facilities to access. Attendees who view the webinar will have an opportunity to receive continuing medical education credit. Many members of the DAB have experience with developing educational webinars and will ensure content is appropriate for dialysis facility medical directors and staff.

FORMATIVE EVALUATION

To study the implementation of the intervention, we will conduct in-person and online formative testing of intervention materials in 3 geographically diverse dialysis facilities to ensure that these materials are appropriate for their target populations (dialysis facility medical directors, staff, and patients). Medical directors will review and provide feedback on the following: (i) the transplantation performance feedback report; (ii) the webinar; and (iii) a baseline survey ([Supplementary Appendix S1](#)) for medical directors for use in the clinical effectiveness study. A structured interview will be conducted to receive feedback on these materials and assess whether there are any missing educational domains from the transplantation performance feedback report or webinar, and if the survey contains items relevant to medical directors and other clinicians involved in transplantation education within the dialysis facility. During formative testing, we will also discuss with dialysis facility medical directors how long they believe it will take to educate staff and patients about the KAS to ensure that we select an appropriate time for follow-up to measure outcomes, using 3 months as an estimate based on previous conversations with members of the DAB.

For formative testing of the educational patient and staff videos, research staff will conduct structured interviews either in person or will administer surveys via email using a Health Insurance Portability and Accountability Act–compliant SurveyMonkey (San Mateo, CA) link. Medical directors will identify staff

who will be asked to view the ~10-minute staff educational video in person (either on an iPad [Apple, Cupertino, CA] or in a lunch-and-learn setting) or via the ASCENT website video link, followed by a structured, in-person interview or SurveyMonkey survey, depending on study site, to assess overall content and style, as well as any missing educational pieces or points of concern.

Dialysis patients will be identified by dialysis facility medical directors or staff and will be asked to watch the patient education video on an iPad or computer during their regularly scheduled dialysis appointment. After viewing videos, structured interviews will be conducted to assess patients' satisfaction and understanding of the video, the impact of the video on patient intent to discuss transplantation with providers, and other ways to improve the video.

RANDOMIZED EFFECTIVENESS-IMPLEMENTATION STUDY

We will test the effectiveness and implementation of the intervention materials¹⁴ among approximately one-half of the estimated 600 randomized dialysis facilities in US ESRD networks to examine whether this intervention improves dialysis facility waitlisting and reduces racial disparity in waitlisting. Because there may be significant heterogeneity in dialysis facilities and patient and staff populations across the participating ESRD networks, we will randomize dialysis facilities that were not included in formative testing within each ESRD network region 1:1 to either the multicomponent intervention (transplantation performance feedback report, webinar, and educational videos) or control group (UNOS educational brochure) ([Supplementary Appendix S2](#)). At baseline, all eligible dialysis facility medical directors in both the intervention and control groups will receive an email from their ESRD network with a link to a web-based survey (Health Insurance Portability and Accountability Act–compliant SurveyMonkey) with informed consent as the first page. We will randomize facilities to either the control or intervention group, and in cases in which 1 dialysis facility medical director or nurse manager oversees multiple facilities that are included in the study, we will assign these facilities to the same study group to avoid cross contamination. Within 1 week of completing the baseline survey, all facility medical directors and/or nurse managers from participating facilities will be emailed and mailed materials associated with their study group assignment, and instructed to share with staff. Intervention dialysis facilities will receive an email containing all intervention materials (transplantation performance feedback report, link to

webinar, patient educational video, and staff educational video), and will also be mailed hard copies of the educational videos in DVD format and performance feedback reports. Control facilities will receive the UNOS pamphlet by e-mail and mail. After ~3 months following the baseline survey, all participating facility medical directors and/or nurse managers will be emailed follow-up surveys by their respective ESRD network contacts to assess secondary outcomes. Staff will be offered the option of a \$10 gift card as incentive for participation for each survey.

SURVEYS

Dialysis Facility Medical Director Baseline Survey

The medical director will answer items regarding their kidney transplantation knowledge and knowledge of KAS, staff training and patient education activities, and intent to refer patients for kidney transplantation evaluation (Table 1; Appendix S1).

Dialysis Facility Medical Director Follow-up Survey

Approximately 3 months after receiving educational materials, medical directors of both intervention and control facilities will receive a follow-up survey with similar questions to the baseline survey to assess knowledge about kidney transplantation and KAS, staff training on the allocation policy, patient education

Table 1. Description of baseline dialysis facility medical director survey for ASCENT Study

Scales	Description	Number of Questions
Dialysis facility characteristics	Assess dialysis facility characteristics, such as size, number of patients and staff, and amenities for patients	14
Perceived staff knowledge and KAS training	Assess staff knowledge of transplant education and training provided, including proportion of staff trained on KAS and delivery of training	4
Perceived patient knowledge, transplantation education, and barriers to transplantation	Assess patient knowledge of transplantation, education provided, including proportion of patients educated about transplantation delivery of education, and patient barriers	4
Medical director knowledge of transplantation, KAS, and racial disparity in transplantation	Assess medical director knowledge of transplantation; knowledge of KAS; and awareness about racial disparities and waitlisting performance at their own facility and nationally	9
Medical director referral practices	Assess medical director's perceived referral practices (demographics of patients referred by race and time on dialysis, and estimates of proportion of patients eligible for, interested in, referred for, and waitlisted for kidney transplantation.	10

KAS, Kidney Allocation System.

of transplantation, intent to refer patients for kidney transplantation, and uptake of intervention and control materials. Intervention and control facilities will also be asked several questions related to implementation (e.g., whether they used each intervention material) corresponding to their study group. The time frame of 3 months for a follow-up of secondary outcomes will be finalized by DAB members and medical directors during formative testing.

CO-PRIMARY OUTCOME MEASURES AND STATISTICAL ANALYSES

Change in Waitlisting and Waitlisting Disparity

We will calculate change in the proportion of patients waitlisted at facilities at 1 year preintervention and 1 year postintervention to determine if intervention facilities had higher waitlisting poststudy compared with control facilities. We will calculate facility racial disparity in waitlisting 1 year preintervention and 1 year postintervention as the difference between the proportions of African American patients versus white patients who were waitlisted within a facility. We chose the period of 1 year for 2 major reasons. First, national surveillance data on waitlisting is only available on an annual basis. Second, we expect the impact of the intervention to be strongest within a timeframe closest to the delivery of the intervention (i.e., within a year of the intervention).

To determine if there is a difference in either of these 2 co-primary outcomes among the intervention versus control facilities, we will use generalized linear models¹⁵ to account for potential correlation of facilities within networks and 2 sample *t*-tests.

SECONDARY OUTCOME MEASURES AND STATISTICAL ANALYSES

Change in Knowledge About Kidney Transplantation and KAS

At baseline and 3 months, we will assess change in transplantation and KAS knowledge among medical directors to determine the degree of knowledge improvement pre- versus poststudy. Items will include general transplantation knowledge, knowledge of KAS, and knowledge about racial disparities and waitlisting performance at their own facility and nationally (Table 1). The knowledge items will be summed, and each dialysis provider will receive a score between 0 and 9. We will calculate average change in knowledge from pre- to postintervention by study group, using *t*-tests to determine if medical directors from intervention facilities were more likely to improve in knowledge compared with providers from control facilities after receiving the intervention.

Change in Staff Training About Kidney Transplantation and KAS

We will assess at baseline and at 3 months what percentage of staff medical directors have been trained about kidney transplantation and KAS, as well as how the training was delivered (e.g., did they hold a training session, send an email, watch video presentations, and so on). We will evaluate changes in how knowledgeable medical providers perceived their staff were (on a scale from 1 [not at all] to 5 [extremely]) on KAS pre- to postintervention. We will conduct paired *t*-tests to determine if differences in the proportion of correct items were greater for intervention facilities versus control facilities.

Change in Patient Education About Kidney Transplantation

We will ask providers at baseline and at 3-month follow-up whether they educated patients on kidney transplantation and how this information was delivered. We will also track visits to the educational video website to determine intervention dose and usage statistics. We will conduct similar analyses to determine if there was a change in the proportion of patients educated about KAS.

Change in Intent to Refer Patients to Kidney Transplantation

We will assess current referral practices of facilities by surveying the facility medical director about the estimated proportion of patients interested, eligible, and referred for transplantation in their facility at baseline and at 3 months postintervention. We will also ask questions about the estimated percentage of patients referred for transplantation by race/ethnicity and time on dialysis. We will conduct paired *t*-tests to determine if differences in the proportion of referred patients was greater for intervention facilities versus control facilities.

OTHER COVARIATES

To explore potential modifiers of the effectiveness of this system-level intervention, we will examine facility characteristics (region, facility size, profit status, and so on), characteristics of patients in facilities (e.g., race, insurance status, comorbid conditions, and so on), and contextual neighborhood characteristics such as poverty, education, or income level. We will include process measures for the intervention (receipt of intervention and self-report) to evaluate the potential for future dissemination of interventions to other US dialysis facilities.

IMPLEMENTATION EFFECT MEASURES

We will use an adaptation of the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework¹⁶ for evaluating the public health impact of this health policy change.¹⁴ This framework builds upon the conceptual models of Rogers¹⁷ and Green and Krueger¹⁸ in this hybrid effectiveness-implementation study. Adoption will be assessed by participation and use of any intervention materials. 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) of receipt and/or use of the feedback report and conduct of staff and patient education. We will explore barriers and facilitators to the use of the reports and education. We will conduct qualitative analyses of select medical directors that were successful intervention implementers ($n = 3$) and non-implementers ($n = 3$) at 1 year via phone interviews and online surveys with medical directors from implementers and non-implementers to assess RE-AIM measures.

SAMPLE SIZE AND POWER

Based on 2014 data, if all 18 ESRD networks participate in the ASCENT study, a total of 1529 dialysis facilities will be potentially eligible for participation, of which 368 have a waitlisting racial disparity (Figure 1). For the primary outcome of overall waitlisting proportion, if an estimated 600 facilities (300 facilities in each study group, with an average of 70 patients per facility) respond, we will be adequately powered (80% at $\alpha = 0.05$) to detect a small difference of 1.9% in the intervention group versus the control group based on a common waitlisting proportion of 10% at baseline (i.e., a waitlisting difference of 10% in the control group and 11.9% in the intervention group). A 2-sided Z-test (pooled) statistic and an intraclass correlation coefficient of 0.06 will be used.

For our other outcome of waitlisting disparity reduction among facilities with a racial disparity at baseline, our sample of 300 in each control and intervention group (total $N = 600$), will achieve 80% power (at $\alpha = 0.05$) to detect a minimum difference of 11% in the waitlisting disparity proportion (percentage of facilities with African American racial disparity) between the intervention and the control groups after 1 year (i.e., a disparity proportion of 21.4% in the intervention group vs. 24.0% in the control group). This calculation assumes a common baseline disparity proportion of 0.24 (24% of facilities have a disparity) at baseline and an intraclass correlation coefficient of 0.06 among patients in a facility. We will use the 2-sided

Likelihood Score Test (Farrington & Manning)¹⁹; the significance level of the test is 0.05.

DISCUSSION

Previous research documented substantial decreased access to kidney transplantation waitlisting and racial disparities in access to kidney transplantation.⁶ A major policy change in the national kidney transplantation allocation system in December 2014 aimed in part at reducing racial disparities among patients waitlisted for transplantation.⁷ Preliminary results suggested that racial disparities might have been reduced in transplantation rates following the implementation of KAS.²⁰ However, due to substantial disparities that existed before waitlisting,^{2,4,21} there were more dialysis patients who could potentially benefit from the changes in KAS by increased access to the deceased donor kidney waitlist.

Previous ESRD network-led quality improvement interventions were successful in helping to improve ESRD patient outcomes, including increasing influenza and pneumococcal vaccination rates,²² fistula placement through the Fistula First initiative,¹¹ and kidney transplantation referrals.²³ Although the support of ESRD networks is a strength for this study, there are several potential limitations of the study design. Network leadership will send both the baseline and follow-up surveys to medical directors to help with study recruitment and data collection, but it is possible that some medical directors will have lower than expected response rates due to differential network responsiveness and because the project is not mandatory, unlike other previous dialysis-facility based projects we have conducted with success.^{10,22,24} To address this issue, the ASCENT research staff will follow up with dialysis facilities that are unresponsive after the initial and reminder emails from their network with additional emails and phone calls to achieve maximum participation. It is also possible that medical directors may forward surveys to nurse managers. We will capture role/title within the survey to address this possibility. In addition, because ESRD network leadership is sending surveys to medical directors, a positive response bias in which facilities report that they improve but may not actually change practice may occur. To minimize this bias, we will ensure that medical directors know that facility-identifiable data are blinded to networks.

An additional limitation could be difficulty to accurately measure uptake of the intervention because of the large-scale nature of the study. For example, dialysis facility staff may report sharing patient videos with patients, but we have no way to track whether

patients watched the video and/or were educated by clinicians about transplantation other than through the medical director survey. However, this study is designed to be an effectiveness-implementation study, with the goal of real-world pragmatic implementation rather than measuring efficacy of the intervention in a controlled setting in which all participants are confirmed to have received the intervention. A strength of this approach is that we will have an estimate of the effectiveness of this intervention approach in the real world, which will provide insight into whether the intervention should be disseminated to all U.S. dialysis facilities through the support of their ESRD networks. An additional potential pitfall of our study is the possibility that knowledge about KAS may increase among medical directors, but that this will not translate into changes in referral and waitlisting for the patient population. Using our process and evaluation measures, we hope to be able to hypothesize reasons for any limits to the success of the intervention.

Despite these limitations, we consider delivery of information about transplantation and the new KAS as a first step toward increasing waitlisting overall and reducing disparities in access to transplantation in the United States. In addition, we will gain essential information from our analyses and implementation measures from surveys and interviews to inform future implementation of the intervention materials to other dialysis facilities across the country. For example, some components of the intervention, such as the patient and staff videos and the medical director webinar, will be made publicly available on a website after study end. If the intervention is effective in improving waitlisting or reducing disparity in waitlisting, ESRD networks could implement the intervention among control dialysis facilities and/or other dialysis facilities not selected for participation in the study.

In conclusion, if effective, the ASCENT study interventions could help extend the reach of a national kidney allocation policy by educating dialysis facility medical directors, staff, and patients about transplantation about the new KAS and thereby increasing the potential impact of KAS on disparity reduction. Conducting this research among dialysis facilities with low waitlisting across the U.S. could help to ensure equitability by reducing racial disparities in, and increasing access to, kidney transplant waitlisting.

DISCLOSURE

SOP is a minority shareholder in Fresenius Dialysis, College Park, Georgia. All the other authors declared no competing interests.

ACKNOWLEDGMENTS

We would like to thank the National Institute on Minority Health and Health Disparities for funding this project (grant no. R01MD010290). Trial Registration: [ClinicalTrials.gov](https://clinicaltrials.gov) number: NCT02879812.

AUTHOR CONTRIBUTIONS

REP participated in study design, intervention development, planning for data collection, helped draft the manuscript, and is the principal investigator. KDS participated in intervention development, planning for data collection, and helped draft the manuscript. MB participated in intervention development, planning for data collection, study design, and helped draft the manuscript. JG and LP participated in intervention development, study design, and planning for data collection. SM, CE, SK, and SP participated in study design and intervention development. TM, GG, AB, GR, TB, and NT participated in intervention development. SC participated in study design.

SUPPLEMENTARY MATERIAL

Appendix S1. ASCENT Baseline Survey for Medical Directors.

Appendix S2. United Network for Organ Sharing (UNOS) Brochure for Control Facilities.

Supplementary material is linked to the online version of the paper at www.kireports.org.

REFERENCES

1. US Renal Data System. *US Renal Data System 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2010.
2. Waterman AD, Peipert JD, Hyland SS, et al. Modifiable patient characteristics and racial disparities in evaluation completion and living donor transplant. *Clin J Am Soc Nephrol*. 2013;8:995–1002.
3. Garg PP, Frick KD, Diener-West M, Powe NR. Effect of the ownership of dialysis facilities on patients' survival and referral for transplantation. *N Engl J Med*. 1999;341:1653–1660.
4. Weng FL, Joffe MM, Feldman HI, Mange KC. Rates of completion of the medical evaluation for renal transplantation. *Am J Kidney Dis*. 2005;46:734–745.
5. Patzer RE, Amaral S, Wasse H, et al. Neighborhood poverty and racial disparities in kidney transplant waitlisting. *J Am Soc Nephrol*. 2009;20:1333–1340.
6. Patzer RE, McClellan WM. Influence of race, ethnicity and socioeconomic status on kidney disease. *Nat Rev Nephrol*. 2012;8:533–541.
7. Organ Procurement and Transplantation Network. *Organ Procurement and Transplantation Network Policies and Reports*. Richmond, VA: US Department of Health and Human Services; 2014.
8. Joshi S, Gaynor JJ, Bayers S, et al. Disparities among Blacks, Hispanics, and Whites in time from starting dialysis to kidney transplant waitlisting. *Transplantation*. 2013;95:309–318.
9. US Renal Data System. *United States Renal Data System, 2015 Annual Data Report: Annual Data Report*. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2015.
10. McClellan WM, Hodgins E, Pastan S, McAdams L, Soucie M. A randomized evaluation of two health care quality improvement program (HCQIP) interventions to improve the adequacy of hemodialysis care of ESRD patients: feedback alone versus intensive intervention. *J Am Soc Nephrol*. 2004;15:754–760.
11. Lynch JR, Mohan S, McClellan WM. Achieving the goal: results from the Fistula First Breakthrough Initiative. *Curr Opin Nephrol Hyperten*. 2011;20:583–592.
12. Foy R, Eccles MP, Jamtvedt G, Young J, Grimshaw JM, Baker R. What do we know about how to do audit and feedback? Pitfalls in applying evidence from a systematic review. *BMC health services research*. 2005;5:50.
13. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*. 2012;50:217–226.
14. Jilcott S, Ammerman A, Sommers J, Glasgow RE. Applying the RE-AIM framework to assess the public health impact of policy change. *Ann Behav Med*. 2007;34:105–114.
15. Liang K-Y, Zeger SL. Longitudinal data analysis using generalized linear models. *Biometrika*. 1986;73:13–22.
16. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. 1999;89:1322–1327.
17. Rogers EM. *Diffusion of Innovations*. 5th ed. New York: Free Press; 2003.
18. Green LW, Krueger M. *Health Promotion Planning: An Educational and Ecological Approach*. Mountain View, CA: Mayfield; 2005.
19. Farrington CP, Manning G. Test statistics and sample size formulae for comparative binomial trials with null hypothesis of non-zero risk difference or non-unity relative risk. *Stat Med*. 1990;9:1447–1454.
20. Massie AB, Luo X, Lonze BE, et al. Early changes in kidney distribution under the new allocation system. *J Am Soc Nephrol*. 2016;27:2495–2501.
21. Johansen KL, Zhang R, Huang Y, Patzer RE, Kutner NG. Association of race and insurance type with delayed assessment for kidney transplantation among patients initiating dialysis in the United States. *Clin J Am Soc Nephrol*. 2012;7:1490–1497.
22. Bond TC, Patel PR, Krisher J, et al. A group-randomized evaluation of a quality improvement intervention to improve influenza vaccination rates in dialysis centers. *Am J Kidney Dis*. 2011;57:283–290.
23. Patzer RE, Gander J, Sauls L, et al. The RaDIANT community study protocol: community-based participatory research for reducing disparities in access to kidney transplantation. *BMC Nephrol*. 2014;15:171.
24. Patzer RE, Paul S, Plantinga L, et al. A randomized trial to reduce disparities in referral for transplant evaluation [epub ahead of print]. *J Am Soc Nephrol*. pii: ASN.2016030320, 2016.